DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 10, 17, and 20

[Docket No. 91N–0447]

RIN 0905–AD59

Civil Money Penalties: Biologics, Drugs, and Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations to establish hearing procedures for use when FDA proposes the imposition of administrative civil money penalties. This rule implements the civil money penalty provisions of several statutes: the National Childhood Vaccine Injury Act of 1986 (NCVIA), the Prescription Drug Marketing Act of 1988 (PDMA), the Safe Medical Devices Act of 1990 (SMDA), the Generic Drug Enforcement Act of 1992 (GDEA), and the Mammography Quality Standards Act of 1992 (MQSA).

EFFECTIVE DATE: August 28, 1995.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 26, 1993 (58 FR 30680), FDA issued a notice of proposed rulemaking (NPRM) to establish procedures for hearings concerning the administrative imposition of civil money penalties by the agency. The NPRM noted that Congress had in recent years given FDA authority to impose civil money penalties in the NCVIA, the PDMA, the SMDA, and the GDEA. FDA requested that comments be filed by July 26, 1993.

Subsequently, a trade association requested an extension of time to file comments, and, in the **Federal Register** of July 27, 1993 (58 FR 40103), the agency extended the deadline for comments to August 25, 1993. In the July 27, 1993, **Federal Register**, FDA corrected an inadvertent error in the proposed rule and added a reference to civil money penalties authority provided for in the MQSA. The MQSA was added to the list of statutes covered by proposed part 17 insofar as the MQSA provided for the administrative imposition of civil money penalties.

Also, as an interim measure pending adoption of proposed part 17, FDA issued a regulation in the **Federal Register** of September 22, 1993 (58 FR 49190), under which it could temporarily conduct civil money penalties hearings pursuant to part 12 (21 CFR part 12). FDA is now revoking procedural regulations that it issued as a temporary measure pending adoption of part 17. This revocation will be effective when these part 17 regulations become effective. Specifically, § 5.99 (21 CFR 5.99) (as published at 58 FR 34212, June 24, 1993) and § 10.50(c)(21) (21 CFR 10.50(c)(21)) (as published at 58 FR 49190) were issued to allow FDA to use part 12 for civil money penalties proceedings on an interim basis. Because this delegation is no longer needed and because retention of these provisions in the Code of Federal Regulations would be confusing, FDA is revoking §§ 5.99 and 10.50(c)(21) when the new part 17 becomes effective.

As to any pending civil money penalty administrative actions that were subject to Notices of Opportunity for Hearing under part 12, when these part 17 regulations become effective, FDA will send letters to the respondents explaining that the agency intends to reinitiate the actions by the complaint and answer process of part 17. None of the pending actions has yet reached the point in the process of publication of a Notice of Hearing under 21 CFR 12.35. Since part 17 was specifically drafted to govern administrative hearings on civil money penalty assessments, its use for pending actions will not prejudice the respondents and will assure consistency in the adjudication of these matters. If, for any reason, there is a stay of the effectiveness of these part 17 regulations, the agency will proceed with the pending civil money penalty administrative actions under current 21 CFR 5.99, 10.50(c)(21), and part 12.

II. Summary of and Response to Comments

In response to FDA's NPRM, the agency received 12 public comments. Most came from device manufacturers or their representatives and device manufacturer trade associations. In addition, one consumer group and the Administrative Conference of the United States commented. What follows is a summary of and response to each comment. Most of those commenting made more than one comment. Except for those comments that are not germane to a particular proposed section of part 17, the comments are considered in connection with the proposed sections to which they are related. In addition to the changes discussed below, a number of editorial changes to the text of the final rule have been made to improve the clarity of the regulation.

A. General Comments on the Preamble

In responding to comments and formulating a final rule, FDA has balanced competing concerns: Namely, the interests of potential defendants in securing as many procedural safeguards as practicable, and the interests of the public in an efficient process that effectively implements the statutes. FDA is very conscious of the need to provide due process for companies and individuals from whom the Government is seeking civil money penalties, and the comments were carefully evaluated against this standard. At the same time, for the civil money penalty remedy to become an effective enforcement tool under the statute, the administrative process must be able to proceed with predictability and efficiency. The industry, as a whole, benefits from an efficient administrative civil penalties process in that such a system will help to maintain consistency in enforcement and thereby protect the majority of companies who stay in compliance against unfair competition from the small minority of firms that do not.

Accordingly, in developing this final rule, FDA has sought to establish an efficient, predictable system that processes cases in a fair and responsible manner, while affording defendants adequate procedural safeguards. As benchmarks, the agency has examined other existing civil money penalty processes, particularly as administered by the Environmental Protection Agency (EPA) and by the Inspector General of the Department of Health and Human Services (HHS). (See HHS regulation on Medicare Exclusions and Civil Money Penalties, 42 CFR part 1005; EPA Civil Penalties and Permit Revocation Regulation, 40 CFR part 22; Program Fraud Civil Remedies Regulation for HHS, 45 CFR part 79; and Program Fraud Civil Remedies Regulation for EPA, 40 CFR part 27).

These regulations provide a variety of procedural rights. FDA has selected from among these various provisions to create a fair hearing process. In response to comments, FDA has made over 25 changes in the final rule (see concluding section of this preamble), in addition to numerous clarifications throughout the preamble. For example, procedural safeguards under part 17 include motions for summary decisions, interlocutory appeal from rulings of the presiding officer, settlement conferences, allowing the parties to determine an appropriate settlement, and providing additional time before the

hearing for the exchange of exhibits, witness lists, and written testimony. All of the EPA and HHS regulations provide for appeal of a presiding officer's initial decision to an appeals board. EPA has an Environmental Appeals Board, while HHS has the Departmental Appeals Board (DAB). FDA has determined (see paragraph 101 below) that it would be an appropriate use of agency resources, as well as an efficient and effective means for handling appeals, to have the DAB serve as the reviewing authority for appeals of decisions by presiding officers on civil penalty actions.

The DAB is generally recognized as a fair and effective adjudicative forum. The DAB is an independent body within HHS with expertise in adjudication of civil money penalties. Accordingly, FDA will use that board, at least initially, for the adjudication of all appeals, including review of default judgments, interlocutory appeals, and appeals from initial decisions under this part. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule in which the Commissioner of Food and Drugs delegates to the DAB the authority for the adjudication of appeals.

While a number of comments to the proposed rule sought procedures virtually identical to procedural rights available in civil litigation in Federal district courts, another comment urged that FDA use a more efficient complaint and answer procedure to streamline the process. These part 17 regulations provide a level of procedural safeguards consistent with that provided in other existing civil money penalties regulations. FDA believes that these procedures afford a respondent an impartial forum for the adjudication of any contested civil money penalty assessments.

1. Two comments questioned the use of administrative civil money penalties in connection with the PDMA and the NCVIA. Those commenting argued that, without specific congressional authority, FDA may not administratively impose civil money penalties, but must seek them through court proceedings. Additionally, another comment argued that FDA may not bind any future statutory grant of civil money penalties authority to part 17 hearing procedures.

FDA disagrees with the position that civil money penalties in connection with the PDMA and the NCVIA may not be imposed administratively, for the reasons stated in the preamble to the NPRM (58 FR 30680 through 30681). FDA acknowledges that the issue has not been directly addressed by the courts, but it agrees with the comment of the Administrative Conference of the United States that ''any challenge to FDA's authority to impose penalties administratively under such statutes (as the NCVIA) should be unsuccessful, *cf., United States* v. *International Harvester*, 387 F. Supp. 1338 (D.D.C. 1974).''

As to implementation of any future civil money penalty statutory provision, FDA has reconsidered the desirability of determining in advance the use of part 17 procedures. Although the use of part 17 procedures to implement future civil money penalty legislation may be entirely appropriate, the agency prefers to preserve the flexibility to determine the procedures that will apply to specific statutory language once enacted. Section 17.1 has been modified to reflect this change.

2. One comment raised the concern that FDA has thus far not been delegated authority to impose civil money penalties by the Secretary of Health and Human Services (the Secretary). The comment's premise is incorrect. The Secretary has delegated to the Commissioner of Food and Drugs (the Commissioner) all authority given the Secretary under the Federal Food, Drug, and Cosmetic Act (the act). (See § 5.10(a)(1).) (See also section 903 of the act (21 U.S.C. 393).) In addition, the Secretary has delegated to the Commissioner authority to perform all functions vested in the Secretary by Congress under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) concerning biologic recall orders. (See 5 CFR 5.10(a)(5).) The Secretary has granted the Commissioner authority to impose civil money penalties under the NCVIA. (See § 5.10(a)(35).) Also the Secretary delegated to the Commissioner authority granted the Secretary under the MQSA, which includes authority to impose civil money penalties. (See 21 CFR 5.10(a)(36).)

3. One comment requested FDA to correct its misquoting in the NPRM regarding the language of section 17(f) of the SMDA (21 U.S.C. 333(g)) by using ''and'' when the statute provided ''or''.

The preamble to the NPRM stated (58 FR 30680 at 30681) that ''civil money penalties are not authorized against persons who violate section 519(a) of the act (21 U.S.C. 360i(a)) * * * or section 520(f) of the act (21 U.S.C. 360j(f)) * * * unless the violation constitutes a significant *and* knowing departure from such requirements or a risk to the public health.'' [emphasis added.] In the July 27, 1993, **Federal Register** (58 FR 40103 through 40104), FDA corrected its inadvertent misquote. Section 17(f) of the SMDA (21 U.S.C. 333(g)(1)(B)) states that civil money penalties shall not apply to any person who violates the requirements of section 519(a) or 520(f) ''* * * unless such violation constitutes (I) a significant *or* knowing departure from such requirements, or (II) a risk to public health * * *.'' [emphasis added]

Conversely, another comment argued that FDA had been inadvertently correct and that the legislative history shows that Congress had actually intended that the violations in question constitute significant *and* knowing departures in order to be punishable by civil money penalties. FDA rejects this argument because Congress' intent is clear from the language of the statute. The legislative history contained in the Conference Report on the SMDA also supports FDA's interpretation (H. Conf. Rept. 959, 101st Cong., 2d Sess. 29 (1990)).

4. Another comment stated that FDA should make clear that civil money penalties are in addition to other remedies available under law, not in lieu of them. FDA agrees that the agency has the authority to use civil money penalties in addition to other judicial and administrative remedies, if appropriate.

5. One comment asserted that violations of medical device reporting, current good manufacturing practice (CGMP), and tracking regulations should be enforced through civil money penalties. FDA agrees that these violations, as well as others, are suitable candidates for civil money penalty actions where authorized by the SMDA. FDA does not intend to rule out the use of civil money penalties in any situation provided for by law. Nor does FDA believe that civil money penalties need be the only remedy it may use to enforce these violations.

6. A comment urged the use of civil money penalties in lieu of warning letters for serious violations of law. FDA advises that its normal practice is to give prior notice by a warning letter or other means before taking more significant enforcement action. However, in the case of very serious violations or other special circumstances, the agency can and will continue to initiate judicial enforcement actions, as may be appropriate with or without the customary prior notice. Civil money penalties were not intended to take the place of warning letters; rather, civil money penalties were intended to assist the agency in safeguarding the regulatory system.

On April 21, 1995, President Clinton directed agencies to use discretion to modify penalties for small businesses. FDA's traditional approach, by which the agency usually provides written

warning to encourage voluntary correction of violations before undertaking the imposition of regulatory sanctions, is in keeping with the President's directive. Also, as discussed in paragraph 25, in addition to establishing the respondent's liability, FDA must prove the appropriateness of the penalty under the applicable statute in administrative civil money penalty actions.

7. One comment requested that the agency set forth specific examples of what will constitute substantial compliance with device tracking regulations such as assigning a percentage of trackable devices that would constitute ''substantial compliance.'' Until FDA has gathered more information on how and to what extent industry has complied with the device tracking regulations, it would be premature for the agency to present such specific, defining examples. FDA declines to do this at this time.

8. Yet another comment proposed that all civil money penalty proposals be cleared through the Department of Health and Human Services prior to implementation. Because the Commissioner of Food and Drugs has been delegated authority to impose civil money penalties as noted in comment 2 of section II.A. of this document, the agency declines to adopt the comment's suggestion. However, as previously noted in the preamble and in paragraph 101 below, FDA has selected the DAB, at least initially, as the reviewing authority for appeals of civil penalty matters. Thus, the DAB's decision will constitute final agency action on contested FDA civil money penalties matters.

9. Several comments noted the absence of any prohibition against ex parte communications with the presiding officer. FDA agrees that restrictions on communications with the presiding officer concerning matters involved in part 17 hearings would be appropriate. Therefore, the agency has added § 17.20 to provide restrictions on ex parte communications.

10. Another comment requested that FDA specifically state that its part 17 regulation does not provide for a private right of action. FDA advises that only Congress can create a private right of action. FDA's regulations are not intended to create such a right.

11. One comment requested that FDA make explicit the authority of the parties and of the presiding officer to use alternative dispute resolution (ADR) in resolving a dispute under part 17. FDA agrees that settlement discussions should be encouraged. Therefore, the presiding officer has been given authority to require the parties to attend settlement conferences, which could include a conference held before an impartial third party, including the presiding officer, another administrative law judge, or a professional mediator. This change is reflected in revised § 17.19, and the agency believes it is a sufficient authorization for the use of ADR procedures.

12. The same comment suggested that FDA clarify whether an appeal to the Commissioner after an initial decision is required before a respondent may seek judicial review. The comment noted that in *Darby* v. *Cisneros*, 113 S.Ct. 2539 (1993), the Supreme Court determined that agency regulations that permit, but do not require, an aggrieved party to seek administrative review of a presiding officer's decision, allow parties to forego the option of administrative review and proceed directly to court. The comment stated a preference for requiring that a party seek administrative review of a presiding officer's decision before going to court, asserting that to be a sensible allocation of responsibilities between courts and agencies. FDA agrees and accepts the suggestion that FDA recast the regulation to ensure that a respondent must request administrative review, which is now made to the DAB, before seeking judicial review. Section 17.51(c) has been revised accordingly.

13. One comment criticized the proposal on grounds that the new part 17 will limit respondents' ability to reasonably contest the agency's allegations, but did not provide specifics to support the assertion. Absent any specific concerns raised by the comment, FDA can only reiterate that the agency believes these procedures reasonably accord due process and offer respondents a fair opportunity to contest the Center's allegations before an impartial presiding officer.

14. One comment took issue with that portion of the preamble of the NPRM which establishes FDA headquarters in Rockville, MD, as the ''venue of choice for hearing procedures.'' The author of the comment urged that hearings take place in the FDA district office in whose jurisdiction the violations are alleged to have occurred. The author further argued that the burden of proof for change of venue from the districts where the alleged violations occurred should rest with the Center rather than the respondent. FDA believes this comment would be more persuasive if the presiding officer were an FDA official from the pertinent district office. However, since the administrative law judge's principal office is in Rockville, MD, and other types of administrative hearings are held there (e.g., hearings under part 12 of FDA's procedural regulations), Rockville, MD, is the most logical and appropriate venue in most cases. FDA notes that the presiding officer has ample discretion to change the venue of the hearing when the Rockville location would present a significant hardship to the respondent.

15. Another comment recommended that FDA establish an internal procedure such as an intra-agency council of senior compliance officials and representatives from the Office of the Chief Counsel to assure the fair exercise of prosecutorial discretion in choosing which civil penalty cases to bring and how large a penalty to seek.

FDA agrees that it is important to exercise enforcement discretion in a fair and reasonable manner. Due to the newness of the civil penalties authority and the lack of FDA precedents in this area, the Office of Regulatory Affairs, Office of Enforcement, will establish coordinating procedures to help assure consistent policies in exercising civil money penalties authority agencywide. This will augment FDA's existing multilevel process that reviews all compliance actions proposed by the field and Centers, including civil money penalties, and which includes review by the Office of the Chief Counsel. If FDA determines that additional review procedures are appropriate after further experience assessing civil money penalties, it can establish those as a matter of internal agency procedure and not regulation.

B. Comments on Specific Sections

Section 17.3—Definitions

16. One comment noted that proposed § 17.3 defined several terms including ''defective,'' ''knowing departure,'' ''significant departure,'' and ''minor violations,'' used in the SMDA, but that the defined terms were not used elsewhere in the proposed rule and, therefore, were unnecessary. The comment urged that it should be made clear that the purpose of the definitions section is to define certain terms used in the SMDA, not terms used in 21 CFR part 17.

FDA agrees that the final rule should clarify that these defined terms apply to specific acts giving rise to civil money penalties, and has revised § 17.3 to reflect these changes. The agency has also modified the definition of ''person'' or ''respondent'' in § 17.3(b) to provide additional examples of potential respondents. Finally, FDA has included by reference in § 17.3 definitions from the act, Title 21, Code of Federal

Regulations, and the PHS Act as they may be used in part 17 proceedings.

17. Another comment took issue with FDA's interpretation of the phrase ''significant departure'' as that term is used at 21 U.S.C. 333(g)(1)(B)(i), which applies to certain recordkeeping and reporting requirements for devices (21 U.S.C. 360i(a)) and to CGMP requirements for devices (21 U.S.C. 360j(f)). Proposed § 17.3(c), which is now § 17.3(a)(1), defined significant departure as a ''departure from requirements which is neither isolated nor inconsequential.'' The comment contended that this definition is likely to be met more often than not in the case of CGMP violations. The comment further argued that this result was contrary to the intent of Congress.

FDA notes that the comment cited no statutory language or legislative history regarding the definition of ''significant departure,'' although a review of the conference report (H.R. Conf. Rep. No. 959, 101st Cong., 2d Sess. 29 (1990)) indicates that Congress did not limit a ''significant departure'' as the comment advocated. FDA believes, however, that the proposed definition could be improved to state that a significant departure includes a single major incident or a series of incidents that collectively are consequential. Section 17.3 has been amended to reflect this interpretation and to clarify that ''significant departure'' is being defined for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(i).

The agency emphasizes that it will not seek assessments of civil money penalties for trivial violations. FDA cannot list all violations that it regards as ''inconsequential,'' and believes that it can and will make reasonable judgments about the importance of violations.

18. One comment requested that the definition of ''knowing departure'' be revised. The author would have ''knowing'' limited to actual knowledge. FDA's proposed definition stated that ''knowing departure means actual knowledge of departure from requirements, or acting in deliberate ignorance of such departure, or acting in reckless disregard of such departure.'' FDA disagrees with the comment. Part 17 defines ''knowing'' consistently with the definitions of ''knowingly'' or ''knew'' in the act as amended by the GDEA in 1992 (now 21 U.S.C. 321(bb)). Nothing in the SMDA or its legislative history suggests that the definition of ''knowing'' in 21 U.S.C. 333(g)(1)(B)(i) was intended to be more restrictive than the definitions of ''knowingly'' or ''knew'' that were added to the act by the GDEA in 1992. FDA has revised the definition of ''knowing'' to clarify that it is being defined for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(i).

19. Another comment maintained that the specific acts giving rise to civil money penalties are defined much too broadly. For example the author of the comment maintained that ''minor violations'' is too broadly defined. In proposed § 17.3, the term ''minor violations'' was defined as ''violations which are isolated and inconsequential.''

The term ''minor violations,'' as used in 21 U.S.C. 333(g)(1)(B)(ii), prohibits the assessment of civil money penalties for minor violations against a person who demonstrates substantial compliance with the requirements of 21 U.S.C. 360i(e) and (f), which relate to device tracking and correction reports. FDA believes that the term ''minor violations'' was used by Congress to prohibit the assessment of civil penalties when a departure from requirements does not rise to a level of single major incident or a series of incidents that are collectively consequential. FDA has revised the final rule (§ 17.3(a)(3)) accordingly and has clarified that ''minor violations'' is being defined for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(ii). FDA notes that this definition of ''minor violation'' is the converse of that adopted for significant departure as used in 21 U.S.C. 333(g)(1)(B).

20. FDA received several comments on the definition of ''defective.'' As proposed, § 17.3(a)(4) defined defective to include ''any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, service, or any defect in mechanical, physical and chemical properties in a device.'' The comments expressed concern about possible broad implications of the proposed definition. In the final rule, FDA has generally retained the proposed definition but clarified that it is included in the defined terms solely for the purpose of interpreting 21 U.S.C. 333(g)(1)(B)(iii), which pertains to the very narrow area of devices that may be prepared, packed or held under insanitary conditions.

One comment argued that the inclusion of ''performance'' in the definition of ''defective'' is overly broad because it includes potential user error in the operation of the device. The comment suggested ''performance'' should be eliminated from the definition.

The intent of 21 U.S.C. 333(g)(1)(B)(iii) was to exempt, from potential assessment of civil penalties, those violations that may result from preparing, packing, or holding devices under insanitary conditions but that do not involve ''defective'' devices.

FDA agrees that performance failures based solely on user error unrelated to the conditions stated in 21 U.S.C. 351(a)(2)(A) or unrelated to problems with the device itself would not be considered a ''defect in performance'' of the device. The agency has revised the definition to make it clearer that ''defect in performance'' refers to ''defect in performance of a device,'' not to defect in performance of a user.

21. The same comment also recommended that the definition of ''defective'' in § 17.3 be amended to add the following statement: ''Defective service and maintenance are included within the scope of this definition only to the extent that such defects are the result of negligence.''

FDA does not believe that a different standard should be applied to service and maintenance than to other activities covered by the definition, such as manufacture and construction. Therefore, the agency is not adopting the suggested amendment to the definition. FDA notes that it does not envision minor deviations from established maintenance or service schedules as being the basis for a civil money penalty action. FDA has clarified the definition of ''defective'' to substitute ''or'' for ''and'' in the phrase ''any defect in the mechanical, physical, or chemical properties of a device,'' since a defect in any one of these properties would cause the device to be ''defective.''

22. Another comment requested that the definition of ''defective'' for purposes of civil money penalty actions incorporate the concept that a device is defective only if the device could reasonably be expected to pose a risk of some harm or not to function as intended because of the defect.

FDA disagrees. FDA will not seek civil money penalties because of trivial defects. However, defects are deviations that can affect the quality or performance characteristics of a device. To require a showing that the deviation is expected to cause harm or malfunction would shift the standard to allow more deviations and to provide less public health protection. The civil money penalty remedy is intended to promote the public health and the adopted definition of ''defective'' for purposes of 21 U.S.C. 333(g)(1)(B)(iii) supports this goal.

Section 17.5—Complaint

23. A comment remarked that § 17.5 does not contain any safeguards to ensure that FDA will only bring actions

in those instances where it believes in good faith after properly conducting an investigation that violations have occurred sufficient to warrant civil money penalties. The comment did not identify what those safeguards should be. Although FDA declines to change § 17.5, as the answer to comment 15 makes clear, FDA's review process for assessing civil money penalties should ensure that the agency will bring such actions only under the circumstances stated in the comment.

24. One comment argued that a complaint should specify ''all facts'' on which FDA is relying. FDA believes that the requirement regarding the contents of the complaint filed under part 17, as proposed, is consistent with other civil processes. For example, a complaint filed under Rule 8(a) of the ''Federal Rules of Civil Procedure,'' requires only ''* * * (2) a short and plain statement of the claim showing that the pleader is entitled to relief * * *.'' The requirements for a complaint are also consistent with the previously cited EPA and HHS Program Fraud Civil Remedies regulations.

FDA intends to file complaints that provide a reasonable description in sufficient detail for a respondent to have a fair understanding of the bases for the action. Moreover, the regulations requiring production of documents (§ 17.23) and exchanges of witness statements and exhibits (§ 17.25) provide for detailed presentations of factual information.

25. The same comment argued that the complaint should justify the amount of civil penalties being sought in accordance with factors identified in § 17.34. Again, FDA believes that a complaint filed under part 17 satisfies the requirements of notice pleading.

FDA recognizes that under the Administrative Procedure Act (APA) (5 U.S.C. 556(d)), as interpreted by the Supreme Court in *Director, OWCP* v. *Greenwich Collieries,* 114 S. Ct. 2251, 2257 (1994), the agency has the burden of proof on the respondent's liability and on the appropriateness of the penalty in light of the factors specified in the statute to be taken into account in determining the penalty. However, the proof that is required by the APA and specified in § 17.33(b) is to be presented by the Center at the time of the hearing, not, as the comment suggests, in the complaint. In order to clarify that the burden of proof referenced in the APA requires the Center to prove the respondent's liability and the appropriateness of the penalty under the applicable statute, § 17.33(b) has been revised to state that ''in order to prevail, the Center must prove respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.''

26. This same comment called for ''the intervention of [an] impartial, non-investigating party regarding whether an administrative complaint is sustainable.'' FDA believes that part 17 already provides for such an ''impartial non-investigating party'' in the form of a presiding officer, who is an administrative law judge qualified under 5 U.S.C. 3105.

27. Another comment objected that the regulation does not provide for a separation of investigatory and adjudicatory functions and stated that civil money penalty proceedings should be among those hearings to which separation of functions applies. FDA has added § 17.20 to provide restrictions on ex parte communications with the presiding officer. Since the DAB will be adjudicating appeals in civil money penalties proceedings, there is no need to adopt separation-of-functions rules in these proceedings.

28. Yet another comment complained that § 17.5(a) fails to identify anyone in FDA management who must approve the decision to impose a civil money penalty. Further, the author of the comment stated a belief that an initial determination of whether or not civil money penalties should be imposed should be made prior to the service of a complaint.

FDA advises that such an initial determination is in fact made. As described in paragraph 15, FDA has an established review procedure for enforcement cases, and that process will have added coordination for civil money penalties cases due to the newness of the authority and the lack of FDA precedents. However, since this is an institutional decision, it is not appropriate to designate a single individual as the agency's decisionmaker.

29. Yet another comment argued that notice pleading such as that provided for in § 17.5(b)(1) is inappropriate in light of the limited discovery provided for under these regulations. The comment called for either a more detailed notice in the complaint or greater discovery.

As discussed in paragraphs 24 and 61, FDA believes expanded discovery and pleading are not necessary. FDA intends to file complaints that provide a reasonable description in sufficient detail for respondents to have a fair understanding of the bases for the action.

30. One comment requested that FDA first put a respondent on notice via a warning letter before it files a claim for civil money penalties. FDA advises that as with FDA's judicial enforcement remedies, it will normally give prior notice by a warning letter or other means, although there may be exceptional circumstances where no prior warning would be given.

Section 17.7—Service of Complaint

31. One comment stated that an affidavit as proof of service should suffice only when service is made by personal delivery. FDA agrees that an affidavit is most appropriate when service is made by personal delivery, and has amended § 17.7(b)(1) to refer to ''personal delivery.''

32. A comment expressed concerns about the costs to be incurred by both the Center and the respondent as a result of these administrative procedures. FDA was mindful of the costs of litigation when it proposed part 17, and has sought to draft these procedures to minimize costs to all concerned. For example, providing for written direct testimony rather than oral direct testimony will significantly reduce the time and costs associated with hearings before the presiding officer.

Section 17.9—Answer

33. One comment argued that § 17.9 should provide for amendments to an answer after submission. FDA advises that it intends that complaints and answers may be amended on motion of the parties throughout the proceeding to conform to proof as justice may require. The ''Federal Rules of Civil Procedure'' follow this method for amendment of pleadings, allowing the motions to be ruled on by the district judge. Similarly, the presiding officer has been given this authority, which is so provided in the final rule (§ 17.9(d)).

34. A comment argued that 30 days is not sufficient to file an answer and that 60 days should be allowed for this purpose. FDA advises that if 30 days is not sufficient, a respondent may apply for more time upon a showing of good cause. (See § 17.9(c).)

35. One comment observed that § 17.9(c) provides for a request for an extension of time within which to file an answer, which request is to be ruled on by the presiding officer, who at that stage will not have been appointed. Under proposed § 17.12, the presiding officer is appointed only after the respondent has answered. The comment requested that the final rule change the procedure.

FDA agrees and is changing the rules to eliminate § 17.12, which is unnecessarily repetitious, to include the

definition of ''presiding officer'' in § 17.3, and to add a provision to § 17.5(d) for the assignment of the presiding officer upon the filing of the complaint.

36. Another comment objected that the proposed rules allow for the default of a respondent who fails to answer a complaint because extraordinary circumstances prevented it from responding within a particular timeframe.

FDA believes the regulation, as proposed, adequately addresses this point. Section 17.9(c) provides for an extension of time within which to file an answer when the respondent can show good cause. Additionally, a respondent may file a motion to reopen a default judgment on the grounds that extraordinary circumstances prevented the respondent from filing an answer. This should provide the relief that the comment requested.

Section 17.11—Default Upon Failure to File An Answer

37. A comment argued that § 17.11 should apply an ''excusable neglect'' standard, not an ''extraordinary circumstances'' test, for determining when relief from default for failure to answer should be granted. FDA prefers the ''extraordinary circumstances'' test, which, although somewhat harder to meet, is justified by the need to encourage respondents to respond in a timely fashion. Additionally, both EPA's and HHS's Program Fraud Civil Remedies regulations use an ''extraordinary circumstances'' test for determining whether to set aside a default judgment.

38. Another comment recommended that the language set forth in § 17.11(a) be modified to contain a requirement for the Commissioner to stay the initial decision of default upon a showing of extraordinary circumstances. FDA has changed § 17.11 regarding the issuance of a decision based upon default to allow the presiding officer to issue the initial decision rather than the Commissioner. The determination of whether to set aside a default judgment is an administrative matter that is better suited for initial review by the presiding officer, and which would be subject to appeal to the DAB.

39. The same comment stated that it is imperative that the term ''extraordinary circumstances'' be fully defined. FDA disagrees. To attempt to define and thus limit the circumstances which will be deemed ''extraordinary'' would be futile. FDA could not possibly anticipate all ''extraordinary circumstances.'' Indeed, such an attempt would probably not be in the interest of respondents as a group, since it would necessarily limit the kinds of circumstances that could be considered ''extraordinary'' and, therefore, in which a default decision could be set aside.

40. Yet another comment requested that no time limit be imposed on the remedy set forth in proposed § 17.11(c) concerning late filing of an answer. FDA disagrees. It is difficult to conceive of ''extraordinary circumstances'' that would justify extending the period for filing an answer or motion before the initial decision becomes final and binding. The regulation sets forth a reasonable procedure for the presiding officer to set aside a default judgment upon the showing of extraordinary circumstances by the respondent.

41. A comment requested that, in order for a default judgment to be entered for failure to answer a complaint, the Center should be required to prove that the complaint was received by the respondent. FDA agrees and has amended § 17.11 accordingly.

42. A comment advocated a provision authorizing a party to move to disqualify a presiding officer in order to assure a fair and impartial hearing. The agency advises that such a motion, carefully documented and based upon good cause, may be filed without a provision in these rules specifically authorizing it. The APA (5 U.S.C. 556(b)) authorizes disqualification of a presiding officer based on the filing in good faith of a timely and sufficient affidavit.

Section 17.13—Notice of Hearing

43. One comment argued that § 17.13 should contain clear standards, with reasonable timeframes, for setting the date, time, and place of the hearing or prehearing conference. Further, the comment suggested that the rules should clarify that the presiding officer sets all hearing dates.

FDA believes that it is currently clear that the presiding officer sets all hearing dates. However, FDA disagrees that the rules should set timeframes for a hearing or prehearing conference. Scheduling depends on many variables, including the schedule of the presiding officer, the length of the hearing, the number of witnesses, etc. The presiding officer needs flexibility to schedule prehearing conferences, testimony, and briefing within the limits set forth in the regulation. Accordingly, additional specific time limitations are not being added to the regulations.

44. One comment requested that § 17.13 explicitly provide that either the notice of hearing or the complaint state specifically and in detail each violation alleged and the factual basis for it. The complaint is required to state the allegations of liability against the respondent, including the statutory basis for liability, to identify the violations that are the basis for the alleged liability, and to state the reasons that the respondent is responsible for the violations. In addition, the notice of hearing requires a statement as to the nature of the hearing and the legal authority and jurisdiction under which the hearing is to be held, as well as a description of the procedures for the conduct of the hearing.

FDA declines to make the requested change. The agency believes that the regulations, including § 17.5(b), require that a complaint provide a respondent with a reasonable description in sufficient detail for a respondent to have a fair understanding of the bases for the action and the issues for the hearing. FDA has clarified in § 17.13 that the notice of hearing is to be served on the respondent after the answer has been filed.

45. Another comment expressed the view that proposed § 17.13(f), which is now § 17.13(e), allows ex parte communications between the Center and the presiding officer without participation or comment by the respondent. The comment requested that ex parte communications not be permitted.

As noted in comment 9 above, § 17.20 has been added to restrict ex parte communications under part 17. However, FDA believes that ex parte contacts are necessary with respect to scheduling of the hearing or prehearing conference, and are contemplated for such administrative purposes. Ex parte scheduling contacts are common at agencies throughout the Federal Government and are not improper under § 17.20. All scheduling decisions made before the notice of hearing is served are subject to change on motion of the respondent, in any event.

Section 17.15—Parties to the Hearing

46. One comment argued that § 17.15 should specify that parties may settle issues prior to the hearing without admitting liability. FDA advises that there is no need to specifically state that the parties can stipulate that a settlement does not carry with it an admission of liability.

The regulation provides that the parties may agree to a settlement of all or a part of the matter. It would be inappropriate to limit by regulation the issues that may or may not be covered in a settlement agreement. The final rule allows for wide latitude in settlement agreements.

47. Another comment requested that FDA specifically state that respondent's counsel may be present and participate at the hearing. FDA agrees, and has amended the regulation to add § 17.15(c) accordingly.

48. A comment recommended that the final rule state whether a settlement pursuant to § 17.15(b) is to be incorporated in the initial decision or is instead to be an independent agreement between the parties. The comment went on to state that, if the settlement is to be incorporated in an independent agreement, the complaint should be dismissed.

FDA advises that a settlement agreement is to be an independent agreement. However, FDA believes that it is not necessary to require the dismissal of the complaint upon the filing of a settlement agreement, as the case will be considered resolved and closed by the filing of the settlement agreement, and the agreement will so provide.

Section 17.17—Summary Decisions

49. A comment objected to the inclusion of a summary decision procedure in proposed part 17. FDA affirms the desirability of summary decision procedures in this context. In many situations, the facts will be undisputed and the only question to be decided is one of law. In such cases, time and money can be saved through a summary decision procedure.

50. The author of the same comment urged that, if summary decision procedures are retained, time to respond to a motion for summary decision should be 30 days, not 10. FDA agrees that 10 days is a short time in which to respond. Therefore, FDA is extending from 10 to 30 days the period in which to respond to a motion for summary decision.

51. Another comment argued that summary judgment for the Center should never be granted without the filing of an affidavit prior to the motion being filed. The comment asserts that failure to require an initial affidavit prior to a motion for summary decision denies the respondent the opportunity to verify the facts set forth in the complainant's pleadings.

The language in § 17.17 setting forth the use of affidavits in filing for a motion for summary decision is virtually identical to the language in Rule 56 of the ''Federal Rules of Civil Procedure.'' Respondent may oppose the motion for summary decision with specific facts or opposing affidavits. The presiding officer may only grant the motion if the pleadings, affidavits, and other material in the record show that there is no genuine issue as to any material fact. Additionally, the presiding officer may direct further evidentiary proceedings on facts still at issue. Accordingly, FDA believes the rule provides adequate safeguards for the due process rights of the respondent.

52. Another comment asked the following: (1) Whether or not a proceeding will be stayed pending an interlocutory appeal granting partial summary decision, and (2) whether judicial review of such a decision is a prerequisite to interlocutory relief.

The decision to stay a proceeding pending appeal is within the discretion of the presiding officer, who will make such a decision based on the facts before him or her at the time. Similarly, FDA believes that in some circumstances it would not be necessary or appropriate to have an interlocutory appeal of a presiding officer's partial summary judgment decision on civil money penalties. A decision by a district court granting partial summary judgment is usually not reviewable by the court of appeals on an interlocutory basis. (See, e.g., *King* v. *California Co.,* 224 F.2d 193 (5th Cir.), *cert. denied,* 352 U.S. 1007 (1955); *Marino* v. *Nevitt,* 311 F.2d 406 (3rd Cir. 1963); *Acha* v. *Blame,* 570 F.2d 57 (2nd Cir. 1978).)

53. Another comment suggested that respondents should be given an opportunity to conduct discovery before FDA may bring a motion for summary decision. FDA advises that the presiding officer has the discretion to deny the motion, grant the motion, or order a continuance to permit affidavits or additional evidence to be obtained under § 17.23(a).

54. Another comment argued that a party should have the option of taking an interlocutory appeal on a partial summary decision order or appealing the issue after a final disposition of the entire matter. FDA believes that a party should be permitted to request interlocutory appeal and has amended § 17.17 and added § 17.18 accordingly.

Economy of effort dictates that partial summary decisions not be appealed routinely to the entity designated by the Commissioner to decide appeals (currently the DAB) on an interlocutory basis, but FDA has agreed to provide the option to permit interlocutory appeal within the discretion of the presiding officer and the entity hearing the appeal. In general, appeal of all issues after a final disposition of the entire matter would reduce unnecessary review time for resolution of civil money penalty cases.

55. One comment expressed a concern about language in the preamble of the proposed rule to the effect that the SMDA permits FDA to bypass the administrative hearing procedure and pursue the imposition of civil money penalties in Federal court. FDA has reconsidered the language stated in the NPRM.

The statute authorizes assessment of civil money penalties in an administrative procedure under the SMDA (21 U.S.C. 333(g)(2)), and this is the most efficient manner of imposing civil money penalties. Judicial review would only occur in the United States Court of Appeals as initiated by the respondent (21 U.S.C. 333(g)(3)).

Section 17.19—Authority of the Presiding Officer

56. A comment objected that § 17.19 does not set forth criteria upon which the presiding officer is to base the assignment of a hearing date. This hearing date, according to the comment, should be within at least 30 days of the giving of written notice in all hearings.

FDA does not believe it is necessary to set forth such criteria. The presiding officer will set dates based upon factors such as his or her own schedule, the length of the hearing, and the number of witnesses. FDA hopes that hearings will be completed expeditiously, but a 30-day period from notice until actual hearing may not be enough time in complex hearings.

57. A comment complained that proposed § 17.19(b)(14), which is now paragraph (b)(15), does not define ''related or similar proceedings.'' FDA chose not to define this phrase because of the difficulty of anticipating all proceedings that might be ''related or similar.'' The comment provides no help in defining the phrase, and the agency does not believe that a definition is necessary.

58. A comment argued that FDA should not have the power to subpoena documents because this would impermissibly broaden FDA's enforcement powers. FDA disagrees. Congress has specifically provided that FDA may subpoena documents under certain circumstances in civil money penalty proceedings. (See 21 U.S.C. 333(g)(2)(A) and 21 U.S.C. 335(b)(1)(A)). This statutory authority is similar to that granted to, and exercised by, other Federal entities, such as the EPA and the HHS Inspector General, and the agency expects to use this authority to the extent provided by law. (See paragraph 60 below.)

59. Yet another comment complained that proposed § 17.19(b)(16), which is now paragraph (b)(17), which permits the presiding officer to ''waive, suspend, or modify any rule,'' gives too much discretion to the presiding officer. The

comment urged that this language be deleted. FDA disagrees. Under 21 CFR 12.70(m), the presiding officer in formal FDA evidentiary hearings has had this authority for many years, and there have been few, if any, allegations that this authority has been abused.

60. One comment opposed the authorization in § 17.19(b)(5) for issuance of subpoenas by the presiding officer in proceedings under section 303(g)(2)(A) of the act (21 U.S.C. 333(g)(2)(A)). The author of the comment stated that this section of the SMDA authorizes only an investigative subpoena, not a hearing subpoena.

FDA disagrees with the comment's interpretation of the SMDA, which, in pertinent part, reads as follows: ''In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to matters under investigation.'' FDA interprets this to allow the agency to issue subpoenas related to a civil money penalty proceeding at any time, including during the adjudication of the penalty. The legislative history indicates that the agency was given authority to subpoena records and witnesses relevant to the civil penalty proceeding. In addition, the statutory phrase ''attendance and testimony of witnesses and the production of evidence'' reflects an intention that the testimony and documents be useable at the hearing itself.

Section 17.23—Discovery

61. A comment stated that FDA should authorize depositions, written interrogatories, and requests for admissions. The comment argued that, while brevity and economy are worthwhile goals, respondents need fuller discovery. The comment asserts that discovery depositions are necessary tools in the formation of a response to a civil money penalties complaint. Specifically, the comment objects to the presentation of hearing testimony orally without the opportunity to depose witnesses before the hearing.

FDA disagrees, and does not believe that additional forms of discovery are necessary for due process to be accorded to respondents. EPA and HHS adjudicative procedures provide these discovery mechanisms under their regulations enacted pursuant to the Program Fraud Civil Remedies Act (31 U.S.C. 3801, *et. seq.*). However, 31 U.S.C. 3803(g)(3)(B)(ii) requires that discovery be authorized to the extent allowed by the presiding officer. The program statutes that these part 17 provisions implement do not require that discovery be provided and FDA is not required to provide for discovery under the APA, which governs these procedures. (See *Pacific Gas and Electric Co.* v. *F.E.R.C.*, 746 F.2d 1383, 1387 (9th Cir. 1984); *McClelland* v. *Andrus*, 606 F.2d 1278, 1285 (D.C. Cir. 1979).)

FDA has discretion to determine the extent of discovery to which a party is entitled in an administrative hearing. In order to allow the parties to present a witness' testimony in the event that a witness would be unavailable for the hearing, FDA has added § 17.23(e) to provide for depositions in limited circumstances. Specifically, the presiding officer may order depositions upon a showing that the information sought is not available by alternative methods and there is a substantial reason to believe that relevant and probative evidence may not otherwise be preserved for presentation by a witness at the hearing.

In order to provide advance notice of each witness' testimony prior to cross-examination at the hearing, FDA has changed § 17.37(b) to require that direct testimony of witnesses be submitted in written form. Section 17.25(a) requires that parties exchange written testimony at least 30 days before the hearing. This should eliminate any concern that a party may be unfairly surprised by a witness' testimony presented at a hearing. Section 17.19(b)(10) has also been changed to authorize the presiding officer to recall a witness for additional testimony upon a showing of good cause. The failure of a party to provide written direct testimony of a witness before a hearing will result in exclusion of the witness' testimony.

The prehearing production of documents and exchange of exhibits by both parties, coupled with the right to cross-examine witnesses at the hearing and recall witnesses upon a showing of good cause, obviates the need for routine depositions, written interrogatories, and requests for admission. Recent changes to the ''Federal Rules of Civil Procedure'' have significantly reduced the number of depositions available to parties in Federal court litigation because of their expensive and time consuming nature (Fed. R. Civ. Proc. 30(a)(2)). FDA believes that its provision for written direct testimony is more cost effective for all concerned. Additionally, to ensure timely exchange of documents between the parties, § 17.23(a) has been changed to require that requests for production of documents be answered 30 days after the request, and that the request be made no later than 60 days before the hearing, unless otherwise ordered by the presiding officer.

62. Another comment argued that § 17.23 should specifically authorize the presiding officer to grant protective orders for trade secrets and confidential commercial information.

FDA agrees and has added a new paragraph to § 17.19(b)(18) to the final rule authorizing the presiding officer to issue protective orders for the protection of trade secrets and confidential commercial information. In order to reflect this change and to eliminate any confusion that resulted from the proposed rule, FDA has revised §§ 17.28, 17.33, and 17.41 to more clearly state the disclosure rules related to part 17 hearings. Additionally, in § 17.23(d)(3) FDA has added that the burden of showing that a protective order is necessary is on the party seeking the order.

63. A comment argued that § 17.23 should specifically exempt ''privileged'' information from access by FDA, even under a protective order. The comment expressed concern that the subsection authorizing the presiding officer to grant a protective order does not address trade secrets and confidential commercial information.

The agency believes that it would not be appropriate for FDA to be denied access to such information. FDA typically has broad access to confidential documents through its regulatory activities and carefully safeguards the confidentiality of those documents. As discussed in comment 62, the presiding officer is authorized to issue a protective order that will prevent public disclosure of such information.

Section 17.25—Exchange of Witness Lists, Witness Statements, and Exhibits

64. A comment took issue with the harshness of the ''extraordinary circumstances'' test for relief for failure to exchange witness lists, statements, and exhibits. The author argued that this relief should be granted only when a party did not substantially comply or noncompliance was in bad faith.

FDA disagrees with the comment's interpretation of proposed § 17.25(b)(2). However, the agency has clarified that § 17.25 (b)(2) and (b)(3) refer to the timely exchange of witness lists under § 17.25(a). The exclusion of other evidence not exchanged in accordance with § 17.25(a) is within the discretion of the presiding officer as noted in § 17.25(b)(1). The agency believes that it is fair and appropriate to grant relief from sanctions for failure to follow the requirements for the timely exchange of witness lists only if there are ''extraordinary circumstances.''

To provide additional time for the parties to prepare for the hearing, FDA has changed the deadline for the exchange of witness lists, exhibits, and prior written statements of witnesses from 15 days to 30 days before the hearing. Section 17.25(c) has also been changed to add that objections to authenticity of documents, exchanged pursuant to § 17.25(a), must be made no later than 5 days before the hearing, or the documents will be deemed authentic.

Section 17.27—Hearing Subpoenas

65. A comment argued that the authority of the presiding officer under § 17.27 to subpoena witnesses broadens FDA's power and is not authorized under the PDMA and the NCVIA. FDA agrees that because neither the PDMA nor the NCVIA grants FDA subpoena powers, § 17.27 should not be made applicable to hearings under these statutes.

FDA is altering § 17.27 to clarify that subpoenas may only be issued by the presiding officer to the extent authorized by law. In order to ensure that a party can prove that a witness has been served with a subpoena, FDA has deleted the provision on service of subpoenas by first-class mail. Revised § 17.27(e) provides that subpoenas shall be served in the manner prescribed for service of a complaint in § 17.7.

Section 17.30—Computation of Time

66. Another comment contended that the ''less than 7 days'' time period stated in proposed § 17.30(b) should be changed to be ''less than 11 days'' if the summary decision response time in § 17.17 remains at 10 days. The comment explained that Rule 6(a) of the ''Federal Rules of Civil Procedure'' uses the ''less than 11 days'' rule specifically to avoid routine requests for extension of the 10-day time for responding to most motions, a period that may include only 5 business days. FDA is changing the summary decision response time to 30 days (see paragraph 50), which should obviate the need for routine requests for extension of the time for responding to motions for summary decision.

Section 17.33—The Hearing and Burden of Proof

67. A comment urged that the presiding officer be required to exclude from the public portion of a hearing all evidence involving what he or she has determined to be trade secrets or confidential commercial information. FDA believes that this is unnecessary.

The agency has revised § 17.33(d) to clarify the scope of information that may be presented in a closed hearing. Under § 17.33 the presiding officer will apply existing laws and regulations to protect trade secrets and confidential commercial information from public disclosure.

68. Yet another comment urged that the Center be required to prove its case by ''clear and convincing evidence'' in light of what the comment refers to as the extremely broad definitions of punishable acts in § 17.3, rather than by a ''preponderance of evidence'' as provided for in the proposal.

FDA believes that the definitions in § 17.3 as revised provide adequate explanation of the defined terms. The acts for which civil money penalties may be assessed, however, are delineated in the various statutory schemes for civil penalties to which part 17 applies. The ''preponderance of evidence'' test is common in many civil proceedings, and is the appropriate standard of proof to be applied by the presiding officer under 5 U.S.C. 556(d). (See *Sea Island Broadcasting of S.C.* v. *Federal Communications Commission*, 627 F.2d 240 (D.C.Cir.), *reh. den.*, *cert. denied*, 449 U.S. 834 (1980).) FDA rejects the comment.

Section 17.34—Determining the Amount of Penalties and Assessments

69. Two comments urged that FDA include ''degree of culpability'' as a factor in determining the amount of a civil money penalty under § 17.34. The degree of culpability is listed as a factor to be considered in 21 U.S.C. 333(g)(2)(B). Because the statutory civil money penalty provisions implemented by this regulation differ, FDA has referenced the statutory scheme under which the penalty is assessed for purposes of determining the amount of penalty, rather than listing factors in § 17.34. Accordingly, FDA rejects the comment.

70. Another comment argued that FDA should factor in the degree to which a respondent has cooperated with FDA. FDA believes that the presiding officer could properly consider the extent of cooperation under the authority provided in § 17.34(c).

Section 17.35—Sanctions

71. Another comment argued that the sanctions section (§ 17.35) is unclear, unnecessarily harsh, and goes beyond the authority delegated to FDA. The comment urged FDA to describe the types of misconduct to which the section applies and to limit sanctions. Such sanction provisions are not novel. For example, they are included in regulations used by EPA and HHS to implement statutory civil money penalty provisions and are designed to enable the presiding officer to manage proceedings effectively. FDA cannot anticipate all types of misbehavior and misconduct that could give rise to sanctions. Further, FDA cannot anticipate what sanctions may be appropriate for particular conduct in a particular situation. The presiding officer must have discretion in this area, and § 17.35 is consistent with the discretion that may be delegated to the presiding officer under the APA (5 U.S.C. 556(c)). FDA therefore declines to accept the comment.

72. A comment argued that FDA needs to provide a means of appeal of an order of the presiding officer imposing sanctions. FDA agrees. Sanctions should be subject to requests for interlocutory appeal. Section 17.18 has been added to allow for interlocutory appeal of matters certified by the presiding officer to need immediate review. However, the rule does not contain a provision for the automatic stay of proceedings before the presiding officer pending appeal.

73. A comment argued that the sanctions listed in § 17.35 are too harsh and that financial penalties might be more appropriate than the loss of the right to defend against or prosecute a civil money penalty claim.

FDA disagrees. The sanctions imposed in § 17.35 are similar to sanctions available under Rule 37 of the ''Federal Rules of Civil Procedure,'' as well as under the Program Fraud Civil Remedies regulations of EPA and HHS, and are a justifiable means of compelling the parties to adhere to the orders and rulings of the presiding officer. As in a proceeding before a judge in Federal court, a party's recalcitrance in disobeying a presiding officer's order in an administrative hearing should not be tolerated. The wide range of sanctions listed in § 17.35 provide flexibility for the presiding officer who might be presented with a party's failure to comply with an order through refusal or neglect.

74. In connection with appellate rights, one comment urged that the parties be afforded the right of judicial review of sanctions imposed during a part 17 hearing.

FDA advises that it has no authority to provide for an appeal to the courts before the agency's final decision is issued. Under § 17.51, the final decision constitutes final agency action which is subject to judicial review. The entire record that forms the basis of the final decision would be available to the reviewing Court of Appeals.

75. Another comment disagreed with proposed § 17.35(g), which provides

that the presiding officer may order a party to pay expenses. This remedy, the author argued, is unenforceable and outside the authority of the Government to provide.

FDA does not agree that it lacks the authority or that such an order of the presiding officer is unenforceable. However, because of the wide range of other sanctions available to the presiding officer for regulating the conduct of the hearing, FDA has made the change requested by the comment and eliminated § 17.35(g) as proposed.

Section 17.37—Witnesses

76. One comment took issue with what was viewed as a requirement that a cross-examining party pay a witness' travel expenses in a situation where direct testimony was submitted in writing. This was not FDA's intention in drafting § 17.37. FDA advises that it intends that a party submitting a witness' testimony in writing is responsible for paying the travel and other expenses of that witness on cross-examination at the hearing. FDA has added § 17.37(g) to clarify its intention.

77. A comment objected to § 17.37 because it could be interpreted to permit rebuttal witnesses and evidence to be submitted without any provision for discovery or identification, as provided for in connection with a party's presentation of its case in chief. FDA advises that, because rebuttal testimony and other rebuttal evidence are limited in scope and in quantity, requirements for notice and discovery are not necessary. Thus, FDA is not specifically providing for discovery or notice of a rebuttal witness' appearance. However, § 17.39(g) allows the presiding officer to permit the parties to introduce rebuttal witnesses and evidence. Implicit in this authority is the authority to set the terms of rebuttal testimony, as justice may require.

78. Yet another comment argued that § 17.37(e) is unduly broad in permitting cross-examination of witnesses on matters other than those within the scope of his or her direct examination. The comment recommended that the rules for cross-examination be predicated upon the ''Federal Rules of Evidence.''

FDA disagrees. In the interest of truth seeking in general and in the interest of procedural economy, FDA prefers § 17.37(e) as proposed. This provision is similar to what EPA and HHS provide in their Program Fraud Civil Remedies of regulations, which give the presiding officer discretion to allow cross-examination of witnesses beyond the scope of their direct examination, rather than limiting cross-examination to only those matters within the scope of direct examination. Otherwise, the opposing party would have to request that a subpoena be issued to a witness by the presiding officer, making the witness its own in a manner that unnecessarily wastes time.

Section 17.39—Evidence

79. One comment objected to § 17.39 to the extent that it renders privileged information nondiscoverable. Section 17.39 is similar to Rule 45 of the ''Federal Rules of Civil Procedure,'' which allows privileged information to be withheld by a person responding to a subpoena. FDA rejects the comment.

80. Another comment objected to language in § 17.39(b), which allows the presiding officer discretion to apply the ''Federal Rules of Evidence.'' According to the comment, the presiding officer is given authority to invoke the ''Federal Rules of Evidence'' in an arbitrary and capricious fashion, which, the comment alleges, abridges the due process rights of both parties. The comment does not, however, provide any details to support its assertion.

FDA disagrees with the comment. To the contrary, under § 17.39(b) the presiding officer is allowed to apply the ''Federal Rules of Evidence'' *when appropriate* which is similar to what EPA and HHS provide in their Program Fraud Civil Remedies regulations. Section 17.39(f) has been changed to substitute the relevant language of Rule 408 of the ''Federal Rules of Evidence'' in place of the reference to Rule 408 in the proposed rule.

Section 17.41—The Administrative Record

81. A comment suggested that § 17.41 should include an explicit exemption to the ''open record'' provision, not subject to the discretion of the presiding officer, if the officer has determined that a portion of the record contains trade secrets or confidential commercial information.

FDA believes this to be a good suggestion, and has so provided. Trade secrets, confidential commercial information, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under 21 CFR part 20 are to be protected from disclosure by order of the presiding officer. Additionally, FDA is amending 21 CFR 20.86, concerning disclosure of information in administrative proceedings, to include part 17.

82. Another comment was concerned that the proposal does not contain a provision authorizing the correction of the hearing transcript and recommended that a provision similar to that contained in 21 CFR 12.98(d) be included in § 17.41. FDA has made the requested change in § 17.41(a).

Section 17.43—Posthearing Briefs

83. A comment objected to the requirement that briefs be filed simultaneously and be limited to 30 pages. According to the comment, these restrictions may prejudice respondents, however, the comment does not state how respondents may be prejudiced.

Under § 17.43, a party may file a longer brief if the presiding officer has found that the issues in the proceeding are so complex or the administrative record is so voluminous as to justify longer briefs. In the absence of a showing that simultaneous briefs will prejudice a party unfairly, FDA sees no reason to change this requirement. Additionally, parties may file proposed findings of fact and conclusions of law. FDA has added to § 17.43 that proposed findings of fact and conclusions of law are also limited to 30 pages unless the presiding officer orders otherwise.

84. Another comment requested that § 17.43 be clarified to state whether the 30-page limitation includes exhibits and attachments. FDA advises that the 30-page limitation does not include exhibits and attachments unless some material is made part of an exhibit or attachment to avoid the 30-page limitation when the material should reasonably have been included in the main portion of the brief itself.

Section 17.45—Initial Decision

85. One comment complained that requiring the presiding officer to decide the case within 90 days will inherently increase the risk of an incorrect result, thereby allegedly denying due process. FDA disagrees. Ninety days should be an ample amount of time for a presiding officer to decide most part 17 hearings. If the presiding officer needs more time, he or she may request that the entity deciding the appeal set a new deadline under § 17.45(c). As stated in the preamble, the DAB will be deciding, at least initially, appeals to the Commissioner for presiding officer decisions under this part, including a presiding officer's request for extending deadlines.

86. Another comment urged FDA to include timeframes for extensions of deadlines for rendering an initial decision. This would assure a speedier process, according to the comment. FDA disagrees. It is difficult if not impossible to set forth in a regulation the criteria for extending timeframes in issuing

hearing decisions. FDA believes that attempting to do so would be unworkable.

87. Yet another comment urged that the initial decision be required to include a discussion of the reasons for the findings and conclusions upon which the decision is based. However, § 17.45 already requires that the initial decision shall contain findings of fact, conclusions of law, and the amount of any penalties imposed. Section 17.45(b) further elaborates on this requirement. In FDA's view, the regulation as proposed does not permit a ''conclusory'' initial decision as the comment seems to presuppose. FDA declines to make the requested change.

88. One comment requested that § 17.45 provide that the initial decision be automatically stayed pending disposition of an appeal or motion for reconsideration. FDA disagrees. The agency does not believe that such a provision is necessary since no civil money penalty can be imposed until there has been final agency action. The initial decision would not become final agency action until any appeal has been acted on, the appeal time has expired, or the respondent has stated an intention not to seek an appeal.

89. Another comment recommended that the word ''may'' (in § 17.45(c)), as it applies to the Commissioner's authority to set a new timeframe for issuing the initial decision, be changed to ''shall.'' This, the comment alleges, would preclude indefinite delay in the issuance of an initial decision. FDA declines to adopt this comment. As indicated under comment 86, FDA believes it would be unworkable to specify all the criteria for determining when timeframes for issuing initial decisions may be extended. FDA reaffirms its intention that all such decisions be made promptly.

Section 17.47—Appeals

90. A comment suggested that § 17.47 should be modified to explicitly provide for an automatic stay of a decision pending an appeal or motion for reconsideration. As stated in a prior response (see paragraph 88 above), such an automatic stay is not necessary.

91. A comment requested that FDA make clear that the Commissioner's decision, which has been delegated to the DAB, not to consider an appeal or the affirmation of the presiding officer's decision on appeal constitutes final agency action subject to judicial review. FDA agrees with the comment and affirms that such events do constitute final agency action. However, the agency sees no reason to amend any regulation to accomplish this. This statement in the preamble should suffice.

92. A comment urged that oral argument of an appeal to the entity designated by the Commissioner to decide appeals (currently the DAB) be allowed. FDA disagrees. Oral argument would not provide the DAB with any additional information that could not be included in the briefs allowed to be filed by the parties under § 17.47. The time required to conduct oral argument does not justify any advantage that might be gained from it.

93. A comment urged that FDA allow 60 days for submission of an appellate brief, especially considering the complexity of likely issues. The comment cites the part 12 practice of allowing 60 days for an appellate brief. FDA disagrees with the comment. The agency believes that issues raised in part 17 hearings will generally be less complex and the volume of testimony smaller than is the case concerning part 12 hearings. Thus, 30 days should be sufficient. If not, § 17.47 provides for extensions upon a showing of good cause.

94. A comment alleged that proposed § 17.47(f), which has been redesignated as § 17.47(g), favors appellees (which it alleges will usually be the Center) by allowing the appellee to make any argument based on the record in support of the initial decision or decision granting summary decision. This, the comment alleges, is unfair because the appellant does not have as much leeway.

FDA disagrees. The appellant has the discretion to determine the specific exceptions to the initial decision that are to be urged on appeal. Section 17.47(c) has been changed to clarify that in the notice of appeal the appellant must identify and support specific exceptions with citations to the record and explain the basis for the exceptions. Since the appellant may urge whatever exceptions it finds appropriate, FDA sees no prejudice in allowing the appellee to make arguments on matters contained in the record. If the entity deciding the appeal (currently the DAB) reverses on issues that the presiding officer considered pivotal, it may still affirm on other grounds if the appellee has raised such other grounds below. There should be no prejudice to either side as both sides have the record before them and can brief on appeal all issues raised in it. As explained in paragraph 95 below, FDA is amending § 17.47(h) to allow the DAB to request additional briefing when an issue has not been adequately briefed by the appellant.

95. Similar objection was raised to § 17.47(g), relating to the appellee's right to make any argument based on the record. The comment stated that if the purpose of this provision is to allow the appellee to anticipate sua sponte decisions by the Commissioner favorable to the appellant, the regulation would be better if recast as allowing the Commissioner to request both parties to address issues not raised by the appellant but determined to be important by the Commissioner.

As previously discussed, the Commissioner has initially designated the DAB to conduct appeals of civil money penalty proceedings under this part. FDA advises that the purpose of the provision in § 17.47(g) is to allow the DAB or other entity deciding the appeal to affirm a decision based on issues raised before the presiding officer but that did not serve as a basis for the presiding officer's decision. This will allow the entity deciding the appeal to overrule the presiding officer on an issue considered pivotal by the presiding officer, but nevertheless to decide the matter in favor of the appellee on other issues based on evidence adduced at the hearing. However, FDA agrees with the comment that the entity deciding the appeal may wish to decide an issue that is not fully briefed by both parties. Therefore, FDA is amending § 17.47(h) to allow that entity discretion to request additional briefing if it: (a) Proposes to affirm an initial decision based on arguments not fully briefed by appellant, and (b) believes that additional briefing is necessary.

96. One comment took issue with the review standard of ''substantial evidence on the whole record'' in § 17.47. The comment argued that the standard of substantial evidence on the whole record is applicable for appellate court review of agency action, but should not be applied by an agency head when the agency does not preside at the evidentiary hearing under the APA, 5 U.S.C. 557(b). The comment went on to state that the burden of proof by a preponderance of the evidence rests upon the complainant under 5 U.S.C. 556(d).

FDA agrees that the appropriate burden of proof before the presiding officer is a preponderance of the evidence, as explained in paragraph 68 above. However, the agency may limit review of the initial decision by the presiding officer if the powers of review have been limited by rule. See 5 U.S.C. 557(b).

FDA has provided that an administrative law judge serve as the fact finder in its civil money penalty actions. As the fact finder, the presiding officer is required to make his or her

findings based on the preponderance of the evidence standard.

When an appeal is made to the DAB under part 17, the DAB, if it decides to review the initial decision, will review disputed issues of fact based on the standard of whether the initial decision is supported by substantial evidence on the whole record. Additionally, the final regulation in § 17.47 has set the standard of review on a disputed issue of law to be whether the initial decision is erroneous. These standards of review are similar to the HHS regulation on appeals of Medicare exclusions, 42 CFR part 1005. The purpose of limiting the scope of the DAB's review of appeals from the presiding officer is to allow the presiding officer to serve as the fact finder and to limit the DAB's reviewing powers to be similar to that of an appellate court. The APA permits the standards of review set forth in § 17.47 for the DAB's review of initial and summary decisions by the presiding officer.

97. Another comment suggested that only the respondent should be permitted to appeal an adverse initial decision. The comment supports its argument by noting that FDA's proposed procedures did not follow the EPA model, which precludes appeals by any party other than the defendant. However, as the comment points out, the EPA provision tracks the statute, 31 U.S.C. 3803(i)(2)(A)(i), with procedures that are statutorily imposed on EPA.

In enacting the civil money penalty provisions in the statutes to which this regulation applies, Congress did not choose to prescribe, other than in a general manner, the administrative procedures to be followed in FDA's assessment of civil money penalties. FDA therefore does not believe the Center should be precluded from requesting the DAB to review an initial decision with which the Center disagrees.

The comment questioned the fairness of allowing the Center to appeal an initial decision in favor of the respondent. Because FDA has revised the appeals provisions in the final rule to designate the DAB, at least initially, to make the decision for the Commissioner, the independent review by the DAB should eliminate speculation of possible bias of the reviewing authority. FDA notes that in civil cases where the United States is a party plaintiff, district court decisions that are adverse to the plaintiff may be subject to appeal by the plaintiff.

For example, the act (21 U.S.C. 360pp(a)) provides that Federal district courts shall have jurisdiction over civil penalties arising from prohibited acts (21 U.S.C. 360oo) pertaining to the regulation of electronic products. If the United States disagrees with a district court judgment as to the amount or lack of penalty, the Federal Rules of Appellate Procedure (Rule 4) authorize an appeal. Under part 17, the Center's right to appeal an initial decision to the DAB is consistent with appellate review authorized for civil cases in Federal district courts.

In cases that are appealed to the DAB, the DAB will normally issue a decision within 60 days. In circumstances where that is not practicable, the DAB will notify the parties of the anticipated time period for ruling on the appeal. Accordingly, § 17.47(j) has been changed to add ''if practicable'' to the 60-day timeframe for the DAB's decision.

98. A comment requested that the time to file an appeal be set at 60 days and that the time to submit a brief be set by the presiding officer. FDA disagrees. The only reason given by the author of the comment for this extension of time is that the issues involved are likely to be more factually and legally complex than those in the typical civil penalty adjudications by other agencies. Further, the comment suggested that a change in the deadlines would avoid routine requests for extension of time.

The agency believes that it is far from clear that the issues involved in part 17 hearings will be more factually and legally complex than those in ''typical civil penalty adjudication.'' However, in order to alleviate the concerns expressed by the comment, FDA changed § 17.47(b)(2) to provide that the 30-day time limit to file the notice of appeal may be extended by the Commissioner or the entity designated by the Commissioner to hear appeals (currently the DAB), within his or her discretion, upon request of the appealing party for good cause shown. In order to ensure that a party has adequate time to respond to the brief filed in support of the appeal, § 17.47(d) has also been changed to allow the entity deciding appeals, within his or her discretion, to extend the time limit for the filing of a brief in opposition to the appeal upon request of the party and a showing of good cause.

99. Another comment recommended that § 17.47(d) not prohibit an appellant's reply brief. The comment stated that, on a practical level, motions for leave to reply will regularly be filed typically accompanied by a brief. Further, the comment argues that, based on past practice, such briefs will be routinely read and considered in any case. FDA agrees and is amending § 17.47 to allow for a short (no more than 10 pages) reply brief.

100. One comment requested that FDA explain more clearly what FDA means in proposed § 17.47(i), which is § 17.47(j) in the final rule, for the Commissioner to ''decline to review the case.'' Indeed, FDA agrees, as the comment presupposes, a decision to decline to review the case has the same legal effect as a decision to affirm the initial decision summarily without further comment. Such a summary decision may be issued without findings of fact or conclusions of law.

In § 17.47(j), FDA has added that a decision by the DAB to decline to review the case shall be the final decision, rendering the initial decision final and binding on the parties 30 days after the declination. For clarification of the possible actions by the entity designated by the Commissioner to decide the appeal, currently the DAB, FDA has changed § 17.47(j) in the final rule to authorize the entity to reverse the initial decision or decision granting summary decision. The proposed § 17.47(i) only provided that the Commissioner could reverse the penalty, but did not explicitly state that the initial decision could be reversed.

101. Another comment opposed any form of summary affirmance of a decision appealed by the Center. The author of the comment alleged that a respondent is entitled to an explanation, however concise, of the reasons why the Commissioner agrees with the presiding officer. According to the comment, the right to omit such an explanation invites cursory review and inappropriately relieves the Commissioner of the burden of responsibility that accompanies the authority to penalize a manufacturer.

FDA rejects the comment and, in so doing, notes that summary affirmances are routinely used by the courts of appeals. Additionally, the EPA and HHS regulations on program fraud that were previously cited provide for similar affirmance of an initial decision by the presiding officer, as does the HHS regulation on Medicare exclusions and civil penalties. FDA continues to believe that a summary disposition is appropriate in various circumstances, such as where issues are not complex and where the evidence heavily favors the appellee.

Underlying the comment may be the concern that the Commissioner might be biased in favor of the Center, when deciding an appeal and using summary affirmances to do so. In order to provide the parties with an independent review of civil penalty appeals, eliminate speculation of possible bias by the reviewing authority, and to allow for

more efficient and effective use of the Commissioner's resources, FDA has elected to designate the DAB to decide appeals under this part, at least initially.

The DAB serves as the reviewing authority for HHS administrative hearings in the previously cited regulations, as does the Environmental Appeals Board for EPA. These Boards have the training and resources to review appeals of civil penalty actions, whereas the Commissioner would be required to set up a separate process for handling civil penalty appeals. The DAB is the logical choice, at least initially, to review appeals of decisions rendered by the presiding officer in part 17 matters, while efficiently and effectively using agency resources.

FDA will use the DAB to decide appeals under part 17 for at least a 4-year period. After 4 years, FDA will evaluate the DAB's role and the Commissioner will determine whether to maintain or alter the delegation to the DAB.

Section 17.49—Delegated Functions

102. A comment suggested that § 17.49 should contain criteria for selecting and delegating authority to an individual under that section. Because FDA is initially providing that the DAB be designated as the entity to decide any appeals under this part, § 17.49 has been eliminated.

103. A comment alleged that § 17.49 allows the Commissioner to assign an agency party with an interest in the litigation to make the final decision on appeal, as long as the individual was not assigned to advise the Center. As noted in paragraph 101, appeals will initially be handled by the DAB. Therefore, any concern about an agency party's influence on the final decision should be eliminated.

104. A comment argued that all civil money penalty assessments should be finally decided by the Commissioner without delegation to another FDA official. As noted in the preceding paragraphs, FDA has provided, at least initially, for appeals to the DAB for a variety of reasons. Therefore, FDA rejects the comments.

Section 17.51—Judicial Review

105. A comment urged that FDA should not be allowed to seek judicial review of an adverse decision. Only a respondent should be allowed to do so, according to the comment. FDA agrees. Section 17.51 should not be interpreted to provide for the Center to seek judicial review. Once a final decision is rendered denying civil money penalties, this becomes the decision of the agency from which there is no judicial appeal by FDA or any of its Centers. Section 17.51 is being amended to clarify this issue.

III. Summary of Changes

1. In § 17.1, concerning the scope of the regulation, the reference to future statutory civil money penalty authority has been deleted. (See comment paragraph 1.)

2. In § 17.3(a), (b), (d), (e), and (f), references to definitions in the applicable statutes and regulations have been added. In § 17.3(a) the definition of ''significant departure'' has been changed to either a single major incident, or a series of incidents that are collectively consequential (paragraph 17). In section 17.3(a) the definition of ''minor violations'' has been changed to ''departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential'' (paragraph 19). Section 17.3(a)(4) has been revised to clarify that ''* * * defect in performance * * *'' refers to ''* * * defect in performance, * * * or service of a device,'' (paragraph 20). In § 17.3(b) scientific or academic establishment or governmental agency or organizational unit has been added to the definition of ''person or respondent'' (paragraph 16). In § 17.3(c) the definition of ''presiding officer'' has been added (paragraph 35). In § 17.3(g) the definition of Departmental Appeals Board has been added (paragraph 101).

3. Section 17.5(c) has been revised to provide for the right of the Center to amend its complaint (paragraph 33). Section 17.5(d) has been revised to provide that the presiding officer is assigned to the case upon filing of the complaint (paragraph 35).

4. Section 17.9(a) is revised to add that the respondents may answer without requesting a hearing. Section 17.9(b) is revised to add that allegations not denied are deemed to be admitted, and that all defenses must be stated in the answer (paragraph 33). Section 17.9(d) was added to provide that respondents may amend their answers (paragraph 33).

5. Section 17.11(a) is revised to add a requirement for proof of service and the authority of the presiding officer to enter default judgments and hold hearings on motions to reopen default judgments (paragraph 38). In § 17.11(a) the reference to the Commissioner has been deleted (paragraph 38).

6. Section 17.12 has been eliminated because the presiding officer is now appointed when the complaint is filed (paragraph 35).

7. Section 17.13 was changed to clarify that the notice of hearing is to be served on a respondent after an answer has been filed (paragraph 44).

8. Section 17.15(b) was revised to add a provision that settlement agreements are to be filed in the docket and do not require ratification by the presiding officer (paragraph 48). Section 17.15(c) was added to clarify that parties may be represented by counsel at the hearing (paragraph 47).

9. In § 17.17(a) the response time to motions for summary judgment has been extended from 10 days to 30 days (paragraph 50). Section 17.17(b) was changed to clarify that summary decision shall be granted when there is no genuine issue as to any material fact (paragraph 51). Section 17.17(e) now limits the ability of a party to obtain interlocutory review of a partial summary decision and refers to the DAB as, currently, the reviewing authority (paragraph 52).

10. New § 17.18 was added to provide for interlocutory appeal from a ruling of the presiding officer (paragraph 54).

11. Section 17.19(b)(3) was changed to authorize the presiding officer to require parties to attend conferences for settlement (paragraph 11). A new § 17.19(b)(10) was added to authorize the presiding officer to allow a witness to be recalled for additional testimony (paragraph 61). Proposed § 17.19(b)(10) through (b)(17) have been renumbered. For consistency of language, in § 17.19(b)(13) (proposed § 17.19(b)(12)) summary ''judgment'' now reads summary ''decision'' when there is no ''genuine'' issue of material fact. A new § 17.19(b)(18) has been added to authorize the presiding officer to issue protective orders (paragraph 62).

12. New § 17.20, has been added to provide restrictions on ex parte communications (paragraph 9).

13. Section 17.21(c)(8) now includes discussion of ''scheduling dates for completion of discovery'' as an authorized use of a prehearing conference (paragraph 61). Section 17.21(d) has been changed to require the presiding officer to issue an order after a prehearing conference (paragraph 61).

14. In § 17.23(a) a requirement has been added that requests for ''production, inspection, and copying'' of documents be made no later than 60 days before the date of the hearing, unless otherwise ordered by the presiding officer.

The party served with the request must respond no later than 30 days after the request has been made (paragraph 61). In § 17.23(c) a reference to new § 17.23(e) has been added. A new § 17.23(d)(3) now places the burden of showing that a protective order is necessary on the party seeking the order

(paragraph 62). Proposed § 17.23(d)(3) has been renumbered (d)(4). Section 17.23(e) has been added to provide for oral depositions under limited circumstances (paragraph 61).

15. Section 17.25(a) has been revised to change the deadline for the exchange of witness lists, prior written statements, and exhibits from 15 days to 30 days before the hearing (paragraph 64). For clarification, § 17.25(b)(2) and (b)(3) have been changed to specifically clarify that the paragraphs concern the admission of testimony by any witness whose name does not appear on the witness lists exchanged under § 17.25(a). Section 17.25(c) now imposes a deadline of ''5 days'' prior to the hearing for objection to authenticity of documents (paragraph 64).

16. Section 17.27(a) now explicitly limits the issuance of subpoenas to when such issuance is ''authorized by law'' (paragraph 65). For ease of proving service, § 17.27(e) has been changed to delete the provision on service of subpoenas by first class mail (paragraph 65).

17. Section 17.28(b) was revised to clarify that a protective order may be issued to protect information that would be withheld from public disclosure under the agency's public information regulations in 21 CFR part 20 (paragraph 63).

18. For clarification, § 17.31(b) was changed to provide that an opposing party must be served with a copy of a document no later than when the document is filed in the docket. Section 17.32(a) now requires that the presiding officer also be served with a copy of documents filed with the Dockets Management Branch.

19. For clarification, in § 17.33(b) and (c) ''is to'' was replaced with ''must''.

Section 17.33(b) has been clarified to add that the Center has the burden of proof to establish that the proposed penalty is appropriate under the applicable statute (paragraph 25). Section 17.33(d) was revised to include a reference to information that would be withheld from public disclosure under 21 CFR part 20.

20. Section 17.34 has been changed to refer to the statute under which the penalty is assessed for purposes of determining the amount of the penalty. The DAB has been referenced as the entity currently designated by the Commissioner to decide appeals under this part in § 17.34(a) and (c) (paragraph 101).

21. Proposed § 17.35(g), which authorized the presiding officer to order the payment of costs as a sanction, has been deleted (paragraph 75). New § 17.35(g) now provides for interlocutory appeal to the entity designated by the Commissioner to decide appeals (currently the DAB) of sanctions imposed by the presiding officer (paragraph 72).

22. Section 17.37(b) now requires, rather than permits, that direct testimony of witnesses be submitted by written declaration under penalty of perjury. The proposed provision in § 17.37(b) on ''sufficient time for other parties to subpoena witness'' has been deleted in light of the addition of new § 17.37(g) (paragraph 76). For clarity, § 17.37(f)(2) was modified to explain more clearly that an officer or employee of a party who is ''designated to be the party's sole representative for purposes of the hearing'' may not be excluded from hearing the testimony of other witnesses. Section 17.37(f)(3) has also been revised to make clear that each party may also have an individual, such as an expert witness, present at the hearing who would not be excluded from hearing other witnesses' testimony. New § 17.37(g) was added to clarify that a cross-examining party need not subpoena the witness, and to require that a sponsoring party produce a witness at its own expense (paragraph 76).

23. In § 17.39(f), a modified version of the language of Rule 408 of the ''Federal Rules of Evidence'' has been substituted for the proposed reference to Rule 408 (paragraph 80). For clarification, in § 17.39(g) a reference to the discretion of the presiding officer was added.

24. In § 17.41(a) a provision has been added to allow for corrections for transcription errors (paragraph 82). Section 17.41(b) has been changed to reference the DAB as the entity currently designated by the Commissioner to decide appeals under this part. Section 17.41(c) has been revised to clarify that upon motion of any party the presiding officer shall protect from disclosure documents that would be withheld from public disclosure under the agency's public information regulations at 21 CFR part 20 (paragraph 81).

25. Section 17.43 has been revised to add a page limit provision for filing of proposed findings of fact and conclusions of law (paragraph 83).

26. Section 17.45(c) has been changed to reference ''the Commissioner or the entity deciding the appeal.''

27. Section 17.47 has been changed to authorize appeals to the DAB instead of to the Commissioner (paragraph 101). Section 17.47(b)(2) now provides that the Commissioner or other entity designated by the Commissioner to hear appeals (currently the DAB) has discretion to extend the 30-day time limit to file an appeal upon request of a party and a showing of good cause.

Section 17.47(c) has been revised to add a page limitation for briefs in support of appeals and a requirement that exceptions listed in the notice of appeal be explicitly supported by citations to the record (paragraph 94). The prohibition on the filing of an appellant's reply brief in proposed § 17.47(d) has been deleted. Section 17.47(d) has been changed to allow the Commissioner or the entity designated by the Commissioner to hear appeals, currently the DAB, to extend the 30-day time limit for the filing of a brief opposing the appeal upon request of the party and a showing of good cause. New § 17.47(e) has been added to provide the right of an appellant to file a reply brief within 10 days of being served with the appellee's brief (paragraph 99). Section 17.47(h) has been renumbered as § 17.47(k) and has been revised to add that the standard of review on a disputed issue of law is whether the initial decision is erroneous (paragraph 101). Proposed § 17.47(e) through (i) have been renumbered. New § 17.47(h) has been added to authorize the entity deciding the appeal (currently the DAB) to request additional briefing by the parties (paragraph 95). Section 17.47(j) has added ''if practicable'' to the 60-day deadline for the decision on appeal. For consistency of language, ''summary judgment'' was changed to ''summary decision'' in § 17.47(j), which was proposed § 17.47(i). In § 17.47(j) explicit language authorizing the entity deciding the appeal (currently the DAB) to reverse the initial decision or decision granting summary decision has been added (paragraph 100). Section 17.47(j) now clarifies that a decision by the entity deciding the appeal (currently the DAB) to decline to review the case shall be the final action of the agency and the initial decision shall be final and binding on the parties 30 days after the declination.

28. Section 17.48 has been changed to reference the DAB as the entity currently designated by the Commissioner to decide appeals under this part.

29. Section 17.49 has been deleted.

30. Section 17.51(a) now states that only a respondent may petition for judicial review or file a petition for stay of a decision by the Commissioner (paragraph 105). New § 17.51(c) makes explicit that exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review (paragraph 12).

31. Section 17.54 has been revised to state amounts assessed under part 17 are to be delivered to the Director of FDA's

Division of Financial Management and then deposited in the U.S. Treasury.

32. In addition, the following revisions have been made to other regulations:

a. Section 5.99, regarding issuance of notices and orders relating to civil money penalties, has been deleted (see the Background section of this document).

b. Section 10.50(c)(21), regarding opportunities for a hearing under 21 CFR part 12, has been deleted (paragraph 9).

c. Section 20.86, regarding disclosure of data and information in administrative proceedings, has been revised to include part 17 (paragraph 81).

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule specifies the procedures to be followed by persons who have the right to a hearing on the administrative imposition of civil money penalties by the agency. As such, the rule does not impose any burden on regulated industry. Because the procedures themselves are protections and do not impose significant costs beyond what the underlying statute imposes, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 17

Administrative practice and procedure, Animal drugs, Biologics, Civil money penalties hearings, Drugs, Generic drugs, Prescription drugs samples, Medical devices.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, Title 21, Chapter 1 of the Code of Federal Regulations is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701–1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

§ 5.99 [Removed]

2. Section 5.99 *Issuance of notices and orders relating to the administrative imposition of civil money penalties under various statutes* is removed.

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

3. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

§ 10.50 [Amended]

4. Section 10.50 *Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing* is amended by removing paragraph (c)(21).

5. New part 17 is added to read as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

Sec.

Authority: Secs. 301, 303, 307, 501, 502, 505, 510, 513, 516, 519, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371); sec. 351, 354, 2128 of the Public Health Service Act (42 U.S.C. 262, 263b, 300aa-28); 5 U.S.C. 554, 555, 556, 557.

§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that as of August 28, 1995, authorize civil money

penalties that are governed by these procedures.

(a) Section 303 (b)(2) through (b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

(b) Section 303(g) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices.

(c) Section 307 of the act authorizing civil money penalties for certain actions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.

(d) Section 351(d)(2)(B) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(e) Section 354(h)(2) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992, authorizing civil money penalties for failure to obtain a certificate, failure to comply with established standards, among other things.

(f) Section 2128 of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers pursuant to that section of the PHS Act.

§ 17.3 Definitions.

The following definitions are applicable in this part:

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(g)(1):

(1) *Significant departure,* for the purpose of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.

(2) *Knowing departure,* for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from a requirement taken: (a) With actual knowledge that the action is such a departure, or (b) in deliberate ignorance of a requirement, or (c) in reckless disregard of a requirement.

(3) *Minor violations,* for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(ii), means departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential.

(4) *Defective,* for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a device, or any defect in mechanical, physical, or chemical properties of a device.

(b) *Person* or *respondent* includes an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, or other legal entity, or as may be defined in the act or regulation pertinent to the civil penalty action being brought.

(c) *Presiding officer* means an administrative law judge qualified under 5 U.S.C. 3105.

(d) Any term that is defined in the act has the same definition for civil money penalty actions that may be brought under that act.

(e) Any term that is defined in Title 21 of the Code of Federal Regulations has the same definition for civil money penalty actions that may arise from the application of the regulation(s).

(f) Any term that is defined in the PHS Act has the same definition for civil money penalty actions that may be brought under that act.

(g) *Departmental Appeals Board (DAB)* means the Departmental Appeals Board of the Department of Health and Human Services.

§ 17.5 Complaint.

(a) The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint signed by the Office of the Chief Counsel attorney for the Center and by filing a copy of the complaint with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

(b) The complaint shall state:

(1) The allegations of liability against the respondent, including the statutory basis for liability, the identification of violations that are the basis for the alleged liability, and the reasons that the respondent is responsible for the violations;

(2) The amount of penalties and assessments that the Center is seeking;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the respondent's right to request a hearing by filing an answer and to retain counsel to represent the respondent; and

(4) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the proposed amount of penalties and assessments, as provided in § 17.11.

(c) The Center may, on motion, subsequently amend its complaint to conform with the evidence adduced during the administrative process, as justice may require.

(d) The presiding officer will be assigned to the case upon the filing of the complaint under this part.

§ 17.7 Service of complaint.

(a) Service of a complaint may be made by:

(1) Certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt; or

(2) Delivery in person to:

(i) An individual respondent; or

(ii) An officer or managing or general agent in the case of a corporation or unincorporated business.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:

(1) Affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery;

(2) A United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or

(3) Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent.

§ 17.9 Answer.

(a) The respondent may request a hearing by filing an answer with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, within 30 days of service of the complaint. Unless stated otherwise, an answer shall be deemed to be a request for hearing.

(b) In the answer, the respondent:

(1) Shall admit or deny each of the allegations of liability made in the complaint; allegations not specifically denied in an answer are deemed admitted;

(2) Shall state all defenses on which the respondent intends to rely;

(3) Shall state all reasons why the respondent contends that the penalties and assessments should be less than the requested amount; and

(4) Shall state the name, address, and telephone number of the respondent's counsel, if any.

(c) If the respondent is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the respondent shall, before the expiration of 30 days from service of the complaint, file a request for an extension of time within which to file an answer that meets the requirements of paragraph (b) of this

section. The presiding officer may, for good cause shown, grant the respondent up to 30 additional days within which to file an answer that meets the requirements of paragraph (b) of this section.

(d) The respondent may, on motion, amend its answer to conform with the evidence as justice may require.

§ 17.11 Default upon failure to file an answer.

(a) If the respondent does not file an answer within the time prescribed in § 17.9 and if service has been effected as provided in § 17.7, the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

(1) The maximum amount of penalties provided for by law for the violations alleged; or

(2) The amount asked for in the complaint, whichever amount is smaller.

(b) Except as otherwise provided in this section, by failing to file a timely answer, the respondent waives any right to a hearing and to contest the amount of the penalties and assessments imposed under paragraph (a) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(c) If, before such a decision becomes final, the respondent files a motion seeking to reopen on the grounds that extraordinary circumstances prevented the respondent from filing an answer, the initial decision shall be stayed pending a decision on the motion.

(d) If, on such motion, the respondent can demonstrate extraordinary circumstances excusing the failure to file an answer in a timely manner, the presiding officer may withdraw the decision under paragraph (a) of this section, if such a decision has been issued, and shall grant the respondent an opportunity to answer the complaint as provided in § 17.9(a).

(e) If the presiding officer decides that the respondent's failure to file an answer in a timely manner is not excused, he or she shall affirm the decision under paragraph (a) of this section, and the decision shall become final and binding upon the parties 30 days after the presiding officer issues the decision on the respondent's motion filed under paragraph (c) of this section.

§ 17.13 Notice of hearing.

After an answer has been filed, the Center shall serve a notice of hearing on the respondent. Such notice shall include:

(a) The date, time, and place of a prehearing conference, if any, or the date, time, and place of the hearing if there is not to be a prehearing conference;

(b) The nature of the hearing and the legal authority and jurisdiction under which the hearing is to be held;

(c) A description of the procedures for the conduct of the hearing;

(d) The names, addresses, and telephone numbers of the representatives of the government and of the respondent, if any; and

(e) Such other matters as the Center or the presiding officer deems appropriate.

§ 17.15 Parties to the hearing.

(a) The parties to the hearing shall be the respondent and the Center(s) with jurisdiction over the matter at issue. No other person may participate.

(b) The parties may at any time prior to a final decision by the entity deciding any appeal agree to a settlement of all or a part of the matter. The settlement agreement shall be filed in the docket and shall constitute complete or partial resolution of the administrative case as so designated by the settlement agreement. The settlement document shall be effective upon filing in the docket and need not be ratified by the presiding officer or the Commissioner of Food and Drugs.

(c) The parties may be represented by counsel, who may be present at the hearing.

§ 17.17 Summary decisions.

(a) At any time after the filing of a complaint, a party may move, with or without supporting affidavits (which, for purposes of this part, shall include declarations under penalty of perjury), for a summary decision on any issue in the hearing. The other party may, within 30 days after service of the motion, which may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision.

The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law.

(c) Affidavits shall set forth only such facts as would be admissible in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated. When a motion for summary decision is made and supported as provided in this regulation, a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing.

(d) If, on motion under this section, a summary decision is not rendered on all issues or for all the relief asked, and if additional facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings on facts still at issue. The facts specified not to be at issue shall be deemed established.

(e) Except as provided in § 17.18, a party may not obtain interlocutory review by the entity deciding the appeal (currently the DAB) of a partial summary decision of the presiding officer. A review of final summary decisions on all issues may be had through the procedure set forth in § 17.47.

§ 17.18 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section, rulings of the presiding officer may not be appealed before consideration on appeal of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the entity deciding the appeal (currently the DAB) if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made, a participant may file a brief on the appeal only if specifically authorized by the presiding officer or the entity deciding the appeal (currently the DAB), and if such authorization is granted, only within the period allowed by the presiding officer or the entity deciding the appeal. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period allowed by the entity deciding the appeal (currently the DAB). The deadline for filing an interlocutory appeal is subject to the discretion of the presiding officer.

§ 17.19 Authority of the presiding officer.

(a) The presiding officer shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The presiding officer has the authority to:

(1) Set and change the date, time, and place of the hearing on reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable time;

(3) Require parties to attend conferences for settlement, to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery consistent with § 17.23;

(8) Regulate the course of the hearing and the conduct of the parties;

(9) Examine witnesses;

(10) Upon motion of a party for good cause shown, the presiding officer may allow a witness to be recalled for additional testimony;

(11) Receive, rule on, exclude, or limit evidence;

(12) Upon motion of a party or on the presiding officer's own motion, take official notice of facts;

(13) Upon motion of a party, decide cases, in whole or in part, by summary decision when there is no genuine issue of material fact;

(14) Conduct any conference, argument, or hearing on motions in person or by telephone;

(15) Consolidate related or similar proceedings or sever unrelated matters;

(16) Limit the length of pleadings;

(17) Waive, suspend, or modify any rule in this part if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(18) Issue protective orders pursuant to § 17.28; and

(19) Exercise such other authority as is necessary to carry out the responsibilities of the presiding officer under this part.

(c) The presiding officer does not have the authority to find Federal statutes or regulations invalid.

§ 17.20 Ex parte contacts.

No party or person (except employees of the presiding officer's office) shall communicate in any way with the presiding officer on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 17.21 Prehearing conferences.

(a) The presiding officer may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the presiding officer shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The presiding officer may use a prehearing conference to discuss the following:

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery and scheduling dates for completion of discovery;

(9) The date, time, and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The presiding officer shall issue an order containing all matters agreed upon by the parties or ordered by the presiding officer at a prehearing conference.

§ 17.23 Discovery.

(a) No later than 60 days prior to the hearing, unless otherwise ordered by the presiding officer, a party may make a request to another party for production, inspection, and copying of documents that are relevant to the issues before the presiding officer. Documents must be provided no later than 30 days after the request has been made.

(b) For the purpose of this part, the term ''documents'' includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form readily accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions, and any forms of discovery, other than those permitted under paragraphs (a) and (e) of this section, are not authorized.

(d)(1) Within 10 days of service of a request for production of documents, a party may file a motion for a protective order.

(2) The presiding officer may grant a motion for a protective order, in whole or in part, if he or she finds that the discovery sought:

(i) Is unduly costly or burdensome,

(ii) Will unduly delay the proceeding, or

(iii) Seeks privileged information.

(3) The burden of showing that a protective order is necessary shall be on the party seeking the order.

(4) The burden of showing that documents should be produced is on the party seeking their production.

(e) The presiding officer shall order depositions upon oral questions only upon a showing that:

(1) The information sought cannot be obtained by alternative methods, and

(2) There is a substantial reason to believe that relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing.

§ 17.25 Exchange of witness lists, witness statements, and exhibits.

(a) At least 30 days before the hearing, or by such other time as is specified by the presiding officer, the parties shall exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including written testimony.

(b)(1) If a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the presiding officer will exclude such evidence if he or she determines that the failure to comply with paragraph (a) of this section should result in its exclusion.

(2) Unless the presiding officer finds that extraordinary circumstances justified the failure to make a timely exchange of witness lists under paragraph (a) of this section, he or she must exclude from the party's hearing evidence the testimony of any witness whose name does not appear on the witness list.

(3) If the presiding officer finds that extraordinary circumstances existed, the presiding officer must then determine whether the admission of the testimony of any witness whose name does not appear on the witness lists exchanged under paragraph (a) of this section would cause substantial prejudice to the objecting party. If the presiding officer

finds that there is not substantial prejudice, the evidence may be admitted. If the presiding officer finds that there is substantial prejudice, the presiding officer may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless a party objects within 5 days prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 17.27 Hearing subpoenas.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may, when authorized by law, request that the presiding officer issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 20 days before the date fixed for the hearing unless otherwise allowed by the presiding officer, upon a showing by the party of good cause. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed for service of a complaint in § 17.7.

(f) If a party or the individual to whom the subpoena is directed believes a subpoena to be unreasonable, oppressive, excessive in scope, or unduly burdensome, or if it wishes to raise any other objection or privilege recognized by law, the party or individual may file a motion to quash the subpoena within 10 days after service or on or before the time specified in the subpoena for compliance if it is less than 10 days after service. Such a filing will state the basis for the motion to quash. The presiding officer may quash or modify the subpoena or order it implemented, as justice may require.

§ 17.28 Protective order.

(a) A party or a prospective witness may file a motion for a protective order with respect to discovery sought by a party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) When issuing a protective order, the presiding officer may make any order which justice requires to protect a party or person from oppression or undue burden or expense, or to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under 21 CFR part 20. Such orders may include, but are not limited to, one or more of the following:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery provided for by this part other than that requested;

(4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;

(5) That the contents of discovery or evidence be sealed;

(6) That the information not be disclosed to the public or be disclosed only in a designated way; or

(7) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the presiding officer.

§ 17.29 Fees.

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in a United States District Court. A check for witness fees and mileage shall accompany the subpoena when served.

§ 17.30 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act or event, and includes the last day of the period, unless either such day is a Saturday, Sunday, or Federal holiday, in which event the time includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and Federal holidays shall be excluded from the computation.

(c) When a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response.

§ 17.31 Form, filing, and service of papers.

(a) *Form.* (1) Documents filed with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, shall include an original and two copies.

(2) The first page of every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the Office of the Chief Counsel, and designation of the pleading or paper (e.g., ''motion to quash subpoena'').

(3) Every pleading shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the pleading was filed, or his or her counsel.

(4) Pleadings or papers are considered filed when they are received by the Dockets Management Branch.

(b) *Service.* A party filing a document with the Dockets Management Branch under this part shall, no later than the time of filing, serve a copy of such document on every other party. Service upon any party of any document, other than service of a complaint, shall be made by delivering a copy personally or by placing a copy of the document in the United States mail or express delivery service, postage prepaid and addressed, to the party's last known address. When a party is represented by counsel, service shall be made on such counsel in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the time and manner of service, shall be proof of service.

§ 17.32 Motions.

(a) Any application to the presiding officer for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, delivered to the presiding officer, and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The presiding officer may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the presiding officer, any party may file a response to such motion.

(d) The presiding officer may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or

following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

§ 17.33 The hearing and burden of proof.

(a) The presiding officer shall conduct a hearing on the record to determine whether the respondent is liable for a civil money penalty and, if so, the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors.

(b) In order to prevail, the Center must prove respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

(c) The respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the presiding officer, who may order closure only to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20 of this chapter.

§ 17.34 Determining the amount of penalties and assessments.

(a) When determining an appropriate amount of civil money penalties and assessments, the presiding officer and the Commissioner of Food and Drugs or entity designated by the Commissioner to decide the appeal (currently the DAB) shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.

(b) The presiding officer and the entity deciding the appeal shall refer to the factors identified in the statute under which the penalty is assessed for purposes of determining the amount of penalty.

(c) Nothing in this section shall be construed to limit the presiding officer or the entity deciding the appeal from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 17.35 Sanctions.

(a) The presiding officer may sanction a person, including any party or counsel for:

(1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with a discovery order, including discovery and subpoena provisions of this part, the presiding officer may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(3) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) The presiding officer may exclude from participation in the hearing any legal counsel, party, or witness who refuses to obey an order of the presiding officer. In the case of repeated refusal, the presiding officer may grant judgment to the opposing party.

(e) If a party fails to prosecute or defend an action under this part after service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

(f) The presiding officer may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion or in compliance with the rules of this part.

(g) Sanctions imposed under this section may be the subject of an interlocutory appeal as allowed in § 17.18(b), provided that no such appeal will stay or delay a proceeding.

§ 17.37 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) Direct testimony shall be admitted in the form of a written declaration submitted under penalty of perjury. Any such written declaration must be provided to all other parties along with the last known address of the witness. Any prior written statements of witnesses proposed to testify at the hearing shall be exchanged as provided in § 17.25(a).

(c) The presiding officer shall exercise reasonable control over the manner and order of questioning witnesses and presenting evidence so as to:

(1) Make the examination and presentation effective for the ascertainment of the truth;

(2) Avoid undue consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The presiding officer shall permit the parties to conduct such cross-examination as may be required for a full disclosure of the facts.

(e) At the discretion of the presiding officer, a witness may be cross-examined on relevant matters without regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, a witness may be cross-examined on relevant matters with regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the presiding officer may order witnesses excluded so that they cannot hear the testimony of the other witnesses. This rule does not authorize exclusion of:

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party designated to be the party's sole representative for purposes of the hearing; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by a party engaged in assisting counsel for the party.

(g) If a witness' testimony is submitted in writing prior to cross-examination, the cross-examining party need not subpoena the witness or pay for his or her travel to the hearing. The sponsoring party is responsible for producing the witness at its own expense, and failure to do so shall result in the striking of the witness' testimony.

§ 17.39 Evidence.

(a) The presiding officer shall determine the admissibility of evidence.

(b) Except as provided in this part, the presiding officer shall not be bound by the ''Federal Rules of Evidence.'' However, the presiding officer may apply the ''Federal Rules of Evidence'' when appropriate, e.g., to exclude unreliable evidence.

(c) The presiding officer shall exclude evidence that is not relevant or material.

(d) Relevant evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue

delay or needless presentation of cumulative evidence.

(e) Relevant evidence may be excluded if it is privileged under Federal law.

(f) Evidence of furnishing or offering or promising to furnish, or accepting or offering or promising to accept, a valuable consideration in settling or attempting to settle a civil money penalty assessment which was disputed as to either validity or amount, is not admissible to prove liability for or invalidity of the civil money penalty or its amount. Evidence of conduct or statements made in settlement negotiations is likewise not admissible. This rule does not require the exclusion of any evidence otherwise discoverable merely because it is presented in the course of settlement negotiations. This rule also does not require exclusion when the evidence is offered for another purpose, such as proving bias or prejudice of a witness or opposing a contention of undue delay.

(g) The presiding officer may in his or her discretion permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the presiding officer pursuant to § 17.28.

§ 17.41 The administrative record.

(a) The hearing will be recorded and transcribed. Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections. Transcripts may be obtained following the hearing from the Dockets Management Branch at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits, and other evidence admitted at the hearing and all papers and requests filed in the proceeding constitute the administrative record for the decision by the presiding officer and the entity designated by the Commissioner of Food and Drugs to decide the appeal, currently the DAB.

(c) The administrative record may be inspected and copied (upon payment of a reasonable fee) by anyone unless otherwise ordered by the presiding officer, who shall upon motion of any party order otherwise when necessary to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20.

§ 17.43 Posthearing briefs.

Any party may file a posthearing brief. The presiding officer shall fix the time for filing such briefs (which shall be filed simultaneously), which shall not exceed 60 days from the date the parties received the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The presiding officer may permit the parties to file responsive briefs. No brief may exceed 30 pages (exclusive of proposed findings and conclusions) unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer briefs, in which case the presiding officer may set a longer page limit. Proposed findings of fact and conclusions of law shall not exceed 30 pages unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer proposed findings and conclusions, in which case the presiding officer may set a longer page limit.

§ 17.45 Initial decision.

(a) The presiding officer shall issue an initial decision based only on the administrative record. The decision shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the allegations in the complaint are true, and, if so, whether respondent's actions identified in the complaint violated the law;

(2) Whether any affirmative defenses are meritorious; and

(3) If the respondent is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering any mitigating or aggravating factors that he or she finds in the case.

(c) The presiding officer shall serve the initial decision or the decision granting summary decision on all parties within 90 days after the time for submission of posthearing briefs and responsive briefs (if permitted) has expired. If the presiding officer believes that he or she cannot meet the 90-day deadline, he or she shall notify the Commissioner of Food and Drugs or other entity designated by the Commissioner to decide the appeal of the reason(s) therefor, and the Commissioner or that entity may then set a new deadline.

(d) Unless the initial decision or the decision granting summary decision of the presiding officer is timely appealed, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after it is issued by the presiding officer.

§ 17.47 Appeals.

(a) Either the Center or any respondent may appeal an initial decision, including a decision not to withdraw a default judgment, or a decision granting summary decision to the Commissioner of Food and Drugs or other entity the Commissioner designates to decide the appeal. The Commissioner has currently designated the Departmental Appeals Board (DAB) to decide appeals under this part. Parties may appeal to the DAB by filing a notice of appeal with the DAB, rm. 637–D, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC 20201, and the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, in accordance with this section.

(b) (1) A notice of appeal may be filed at any time within 30 days after the presiding officer issues an initial decision or decision granting summary decision.

(2) The Commissioner or the entity designated by the Commissioner to hear appeals may, within his or her discretion, extend the initial 30-day period for an additional period of time if the Center or any respondent files a request for an extension within the initial 30-day period and shows good cause.

(c) A notice of appeal shall be accompanied by a written brief of no greater length than that allowed for the posthearing brief. The notice must identify specific exceptions to the initial decision, must support each exception with citations to the record, and must explain the basis for each exception.

(d) The opposing party may file a brief of no greater length than that allowed for the posthearing brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief, unless such time period is extended by the Commissioner or the entity designated by the Commissioner to hear appeals on request of the opposing party for good cause shown. Any brief in opposition to exceptions shall be filed with the Dockets

Management Branch and the DAB (addresses above).

(e) The appellant may file a reply brief not more than 10 pages in length within 10 days of being served with appellee's brief.

(f) There is no right to appear personally before the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB).

(g) The entity deciding the appeal will consider only those issues raised before the presiding officer, except that the appellee may make any argument based on the record in support of the initial decision or decision granting summary decision.

(h) If on appeal the entity deciding the appeal considers issues not adequately briefed by the parties, the entity may ask for additional briefing. However, no such additional briefs will be considered unless so requested.

(i) If any party demonstrates to the satisfaction of the entity deciding the appeal (currently the DAB) that additional evidence not presented at the hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the entity deciding the appeal may remand the matter to the presiding officer for consideration of the additional evidence.

(j) The Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) will issue a decision on the appeal within 60 days, if practicable, of the due date for submission of the appellee's brief. In the decision, the entity deciding the appeal may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by the presiding officer in the initial decision. If the entity deciding the appeal declines to review the case, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after the declination by the entity deciding the appeal.

(k) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

§ 17.48 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the presiding officer or by any of the parties is grounds for vacating, modifying, or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the presiding officer or the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) to be inconsistent with substantial justice. The presiding officer and the entity deciding the appeal at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

§ 17.51 Judicial review.

(a) The final decision of the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) constitutes final agency action from which a respondent may petition for judicial review under the statutes governing the matter involved. Although the filing of a petition for judicial review does not stay a decision under this part, a respondent may file a petition for stay of such decision under § 10.35 of this chapter.

(b) The Chief Counsel of FDA has been designated by the Secretary of Health and Human Services as the officer on whom copies of petitions for judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the entity deciding the appeal (currently the DAB).

(c) Exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review.

§ 17.54 Deposit in the Treasury of the United States.

All amounts assessed pursuant to this part shall be delivered to the Director, Division of Financial Management (HFA–100), Food and Drug Administration, rm. 11–61, 5600 Fishers Lane, Rockville, MD 20857, and shall be deposited as miscellaneous receipts in the Treasury of the United States.

PART 20—PUBLIC INFORMATION

7. The authority citation for part 20 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905.

§ 20.86 [Amended]

8. Section 20.86 is amended by revising the first sentence to read as follows:

§ 20.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. * * *

Dated: July 12, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–18325 Filed 7–26–95; 8:45 am]

BILLING CODE 4160–01–P